Development and Feasibility of the Wheelchair in-Seat Activity Tracker (WiSAT) Clinical Protocol

by

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Wheelchair users are at a higher risk for developing pressure injuries due to reduced mobility, impaired sensation, and spending a large portion of their time in the seated position. Pressure injuries can be a very costly and life threatening complication for wheelchair users. One strategy for pressure injury prevention is to complete weight shifts and pressure reliefs. Literature shows that there is a low adherence to the pressure relief and weight shift clinical guidelines by wheelchair users. The Wheelchair in-Seat Activity Tracker (WiSAT) has been developed to help wheelchair users track their in-seat movement and help aid in the prevention of developing pressure injuries. The objective of this preliminary study is to examine the WiSAT system's potential to impact behavior using a single-subject design and evaluate the clinical protocol developed to assess the effect of the WiSAT system on in-seat movement behavior.

One individual who used a manual wheelchair participated in the study. He completed two study visits and used the WiSAT system in his natural environment for 5 months. The results of his participation revealed that the WiSAT system may have an impact on in-seat behavior, but more subjects are needed to establish the WiSAT system's effectiveness. In addition, throughout the recruitment process and the participant's equipment trial, numerous protocol issues were discovered and resolved. The modifications and improvements made as a result of this preliminary study will reduce the extent of future problems with the WiSAT equipment as well as minimize the amount of missing data.

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1.0 INTRODUCTION

In 2010, 3.6 million individuals over the age of 15 were reported to use a wheelchair in the United States (Brault, 2012). And since 2010, the percentage of individuals with an ambulatory disability in the United States has increased (Cornell University, 2018). Wheelchair users who lack sensation or have paralysis in their lower limbs are at increased risk for the development of pressure injuries (Consortium for Spinal Cord Medicine Clinical Practice Guidelines, 2014; European Pressure Ulcer Advisory Panel, National Pressure Ulcer Advisory Panel, & Pan Pacific Pressure Injury Alliance, 2019). Investigators at Georgia Institute of Technology (Georgia Tech) have developed a new piece of technology, the Wheelchair in-Seat Activity Tracker (WiSAT) to help prevent the formation of pressure injuries.
WiSAT is designed to monitor and provide visual feedback on weight shift behavior and in-seat movement activity. This innovative system hopes to promote effective weight shift and pressure relief behaviors.

The Department of Defense (DoD) funded the *Development of the Wheelchair in-Seat Tracker* study to evaluate the effectiveness of WiSAT and improve WISAT design through user feedback. This study will be conducted at the University of Pittsburgh in Pittsburgh, Pennsylvania and the Edward Hines Jr. VA Hospital in Chicago, Illinois. Both sites will aim to recruit 38 participants, totaling to 76 participants. Due to the complexity of the equipment and the newly designed smartphone application, a preliminary single-subject design study was conducted as the University of Pittsburgh prior to the start of the larger clinical study.

The primary objective of this preliminary single-subject study was to evaluate the effect the WiSAT system has on in-seat movement behavior. The hypotheses were as follows:

1. The use of the WiSAT mobile application will demonstrate an increase in the user's weight shift frequency.
2. The use of the WiSAT mobile application will demonstrate an increase in the user's activity score.

The secondary objective of this preliminary study was to examine the feasibility and acceptability of the WiSAT clinical study protocol.

2.0 BACKGROUND

2.1 PRESSURE INJURY ETIOLOGY

The skin consists of two layers, the epidermis (outermost layer) and the dermis. Under the dermis is a layer of adipose tissue, muscle and then bone. When a surface, such as a seat or bed, comes in contact with the body, the skin and the tissue layers under the skin are at risk for a pressure injury. Pressure injuries, also previously known as pressure ulcers, are caused by damage to the skin and underlying tissue due to prolonged pressure or shear. These injuries typically occur at the site of bony prominences. In addition to pressure and shear forces from a surface, there are numerous intrinsic and extrinsic risk factors that contribute to the development of pressure injuries (Consortium for Spinal Cord Medicine Clinical Practice Guidelines, 2014; European Pressure Ulcer Advisory Panel et al., 2019; Grey, Harding, & Enoch, 2006).

When the body comes in contact with a solid surface, the tissue layers are mechanically loaded by a force perpendicular to the interface surface, pressure, and a force parallel to the interface surface, shear. These forces cause deformation not only to the skin, but also the tissue layers below the skin. The amount of deformation and the impact of the deformation is determined by the duration of the mechanical loading along with the magnitude or intensity of the mechanical loading. Sustained tissue deformation can distort the cells and cause deformation-induced cell death. Deformation can also cause ischemia, which is a restriction of blood supply to tissues. This obstructs tissues from receiving nutrients and oxygen as well as hinders tissues from removing waste. Ischemia can also ultimately lead to cell death and tissue damage. As tissue deformation persists, the tissue layers become more susceptible to damage and necrosis, eventually forming a

pressure injury (European Pressure Ulcer Advisory Panel et al., 2019). Pressure injuries can form at the outermost skin layer or at a tissue layer below the epidermis. Numerous studies have revealed that the muscle tissue layer is more vulnerable to damage than skin tissue (Consortium for Spinal Cord Medicine Clinical Practice Guidelines, 2014; European Pressure Ulcer Advisory Panel et al., 2019).

The underlying causes that impact the development of pressure injuries are complex. Pressure injuries are not only formed as a result of pressure and shear forces, but also there are multiple confounding variables. Several known intrinsic and extrinsic risk factors have been shown to be associated with pressure injuries. Intrinsic risk factors are inherent to each individual based on his/her body condition and health. In general, these are difficult to change. An example of an intrinsic risk factor is decreased muscle mass. Muscle mass affects pressure injury development because it normally acts as a cushion to help protect bony prominences. After paralysis, individuals tend to lose muscle mass in the section of their body that is paralyzed. This loss leads to increased pressure on thinner tissue layers, which ultimately expedites pressure injury formation. Some additional intrinsic risk factors are being overweight, being underweight, decreased circulation, poor overall health or nutrition, nerve damage that reduces pain or feeling, dry skin, aging, previous skin breakdown, and depression. Some extrinsic factors that have been found to affect pressure injury formation include prolonged exposure to pressure, friction, and moisture as well as the type of surface in contact with the body. An individual's risk can be assessed by clinicians using various validated questionnaires and scales, like the Braden Scale (Grey et al., 2006).

Once exposed to pressure and shear, the skin and tissue layers under the skin are at risk to develop a pressure injury. The rate, intensity, and type of pressure injury that forms is dependent on the tissue composition as well as the internal and external risk factors (European Pressure Ulcer

Advisory Panel et al., 2019). In 2016, the National Pressure Ulcer Advisory Panel released updated information regarding the classification of pressure injuries. The classification involves four different stages along with unstageable and suspected deep tissue injury to describe pressure injuries. A Stage 1 pressure injury is defined as intact skin with a nonblanchable erythema, or redness. Stage 2 consists of a partial loss of skin in which the dermis is affected and potentially visible. The wound may appear pink or moist or it may present as a blister. Once the wound has reached the adipose tissue layer, it is considered a Stage 3 injury. Stage 4 is defined as full skin and tissue loss that exposes fascia, muscle, tendon, ligament, cartilage, or bone. If slough or eschar is in the wound and the debris obscures the ability to stage the wound, the pressure injury is considered an unstageable full-thickness pressure injury. Lastly, a deep tissue pressure injury is described as intact skin with nonblanchable deep red or purple discoloration. Non-intact skin that exposes a dark wound bed or blood blister is also classified as a deep tissue injury. Pressure injury classification defines the injuries physical appearance as well as the degree of tissue damage caused by the pressure and shear forces (Consortium for Spinal Cord Medicine Clinical Practice Guidelines, 2014; Edsberg et al., 2016; European Pressure Ulcer Advisory Panel et al., 2019).

If not treated properly, the tissue breakdown could allow for the growth and infection of life-threatening bacteria (Grey et al., 2006). Pressure injuries have been known to cause recurrent hospitalization, surgeries, and life-threatening complications such as sepsis and death. Additionally, treatment for pressure injuries can also be quite costly. In the United States, pressure injury care is estimated to be between $500 to $152,000 for each pressure injury, averaging about $11.6 billion each year (European Pressure Ulcer Advisory Panel et al., 2019).

2.2 PRESSURE INJURIES AND WHEELCHAIR USE

As mentioned, 3.6 million individuals in the United States have been reported to use a wheelchair (Brault, 2012). Due to reduced mobility, loss of muscle mass, potential loss of sensation, and spending a large portion of time in the seated position, wheelchair users are at higher risk for developing seating-related pressure injuries on their buttocks (Mortenson et al., 2018; Sharon E Sonenblum, Sprigle, & Martin, 2016; Stephens, Bartley, Betteridge, & Samuriwo, 2018; Taule et al., 2013). It is natural for the human body to unconsciously reposition itself while in the seated posture to relieve pressure. But when an individual has impaired sensation or motor function in their lower limbs, their body does not initiate this natural pressure relief behavior as often or potentially at all. For this reason, wheelchair users with impaired sensation or motor function in their lower limbs need to self-initiate pressure reliefs and weight shifts while seated to prevent the formation of pressure injuries (Schofield, Porter-Armstrong, & Stinson, 2013; Sharon E Sonenblum et al., 2016; Taule et al., 2013; Yang, Chang, Hsu, & Chang, 2009).

There are several prevention methods for pressure injuries for both power and manual wheelchair users. These include skin checks, skin protective support surfaces, and weight shifting education and training. Skin inspections are recommended to be completed daily, with special attention to areas with bony prominences, such as, the back of head, shoulder blade, sacrum, hips, ischium, and heels that should be regularly checked. Mirrors or cameras may be utilized to complete thorough self-inspections, while others may rely on a caregiver to complete their skin inspections (Consortium for Spinal Cord Medicine Clinical Practice Guidelines, 2014). In addition to skin inspections, the surface at which the individual sits or lays on throughout the day is also important. There are various mattresses and cushions that are designed to enhance pressure distribution, alter the parts of the body that bear load, minimize shear forces, and/or help control

the interface temperature and humidity levels. Skin protection support surfaces can be made of several different materials, including fluid, gel, and foam. The surfaces can be non-powered or powered (i.e., an alternating air mattress or cushion). Support surfaces are typically chosen based on the individual's activity level and risks associated with pressure injury formation (European Pressure Ulcer Advisory Panel et al., 2019). Lastly, weight shifting and pressure relief techniques are taught to individuals at risk for developing pressure injuries. Recommendations for frequency and duration of these behaviors vary among different clinics and hospitals (Mortenson et al., 2018). Current clinical guidelines recommend individuals in the seated position to weight shift every 15 - 30 minutes for at least 30 seconds, however, other research shows that to receive full recovery of tissue oxygenation each weight shifts duration should be longer than 1 minute (up to 4 minutes). Some pressure relief methods for manual wheelchair users include full or partial forward leans and full or partial leans to both sides. These behaviors are completed to either fully or partially unload the ischial tuberosities and sacrum (Consortium for Spinal Cord Medicine Clinical Practice Guidelines, 2014; Lange & Minkel, 2017). For power wheelchair users, tilt and recline are used to redistribute pressure and perform practical pressure reliefs. According to the "Prevention and Treatment of Pressure Ulcers: Clinical Practice Guideline" created by the collaboration of national leaders in pressure injury research and knowledge, a minimum tilt of 30°is required to achieve a clinically important reduction in pressure on the ischial tuberosities (European Pressure Ulcer Advisory Panel et al., 2019).

Full-time manual wheelchair users spend an average of 9-10 hours in their wheelchairs on a typical day. However, research shows that there is a low adherence to users practicing clinician-taught, in-seat movements, such as weight shifts and pressure reliefs, to unload the users' bony prominences while in their wheelchairs (Sharon E Sonenblum et al., 2016; Stephen Sprigle &

Sonenblum, 2016; Stinson, Ferguson, & Porter-Armstrong, 2018; Yang et al., 2009; Yang, Chou, Hsu, & Chang, 2010). Similar to manual wheelchair users, power wheelchair users have also demonstrated a low observance of weight shift routines by underperforming weight shift frequency or not applying large enough angles of tilt and/or recline to effectively relieve pressure (Ding et al., 2008; Schofield et al., 2013; S. E. Sonenblum, Sprigle, & Maurer, 2009; Stephen Sprigle & Sonenblum, 2016). Studies with self-report data from wheelchair users have also shown that individuals with neurological injuries who have been educated to preform pressure reliefs, generally perform reliefs less than once per hour which is less than the typical clinical recommendation (Vos-Draper & Morrow, 2016).

2.3 RELATED RESEARCH

Presently, there have been a few tools developed that measure in-seat behavior of wheelchair users. The most established technology is Permobil's Virtual Seating Coach. The Virtual Seating Coach was developed by the Human Engineering Research Laborites (HERL) and adopted by the wheelchair manufacture Permobil. It is now incorporated into Permobil's power wheelchairs. The Virtual Seating Coach is programmed by a clinician with a weight shift routine involving specific time intervals between shifts and seat angles for the shifts. Alerts and feedback are provided to the end-users through a mobile application on their smartphone (Liu, 2014; Permobil, 2019; Wu, Liu, Kelleher, Pearlman, & Cooper, 2016).

SENSIMAT is another pressure relief tracker currently on the market. It involves a mat containing pressure sensors that is paired with a smartphone mobile application. The mobile application allows users to set pressure relief goals and sends the user alerts throughout the day.

Additionally, the app transmits the user's pressure relief data to the user's healthcare provider (SENSIMAT Systems). One study was found that utilized the SENSIMAT system with 15 participants. Prior to this study, the researchers pilot tested the system on 11 individuals to ensure that the device captured offloading behavior. Additionally, in this study, participants used the system for 2 hours and recorded an activity log. The activity log confirmed that the system was capturing the subjects' activity. However, the main objective of the study was not to establish feasibility or reliably of the system, so the study only briefly discussed the SENSIMAT system's ability to accurately capture activity (Gabison, Mathur, Nussbaum, Popovic, & Verrier, 2017). Although this device is currently on the market, no literature could be located regarding thorough reliability testing of the device.

There have been several other pressure sensor devices developed to help provide weight shift training and feedback on weight shift behaviors. Vos-Draper and Morrow reviewed the devices created prior to 2016 (Vos-Draper & Morrow, 2016). Devices ranged in the type of feedback they provided, such as, alarms, visual, verbal, tactile, and printouts. The devices reviewed were not developed for long-term use, however, the literature review did conclude that feedback and prompts do have a positive effect on movement. Additionally, Vos-Draper and Morrow call for "Additional technologies, such as activity monitors combined with seat interface pressure mapping (IPM), could produce powerful behavior change drivers through real-time, immediate information about the need to shift weight or about the effectiveness of a weight shift when it is done", demonstrating the need for technology like WiSAT. They also emphasize the opportunities that smartphone technology presents (Vos-Draper & Morrow, 2016).

A few more similar devices have emerged. The Tongue Display Unit (TDU) is a wireless lingual device that is placed in an individual's mouth. Since individuals with impaired sensation

in their lower limbs do not receive signals from their body regarding the need to weight shift, this device delivers an electrostimulation to the tongue to remind the individuals to shift their weight. The device is paired with a pressure map installed in the individual's wheelchair cushion. The TDU device was able to reduce prolonged excessive pressure, but it was also deemed as inconvenient by the end-users. In the future, the designers of TDU plan to redesign the device to make it more convenient for use, potentially redesigning it to part of a watch or smartphone (Moreau-Gaudry et al., 2018). The TDU does not appear to be currently commercially available.

Lastly, investigators at the Minneapolis VA Health Care System developed the Comprehensive Mobile Assessment of Pressure (CMAP). CMAP involves a pressure mat that is placed on top of the wheelchair cushion and communicates via Bluetooth to a smartphone mobile application. The device provides continuous, real-time feedback of seat interface pressure 24 hours a day. The investigators observed overall positive results regarding the satisfaction of users with their device. Manual wheelchair and power wheelchair users expressed different uses for the device. Additionally, there was some negative feedback regarding the hardware and connectively of the system (Olney et al., 2019). The CMAP does not appear to be currently commercially available.

Although there are similar systems to WiSAT being developed and on the market, WiSAT is still a competitive product. Some of the devices are reported to contain hardware and connectivity issues and not all of the devices are compatible with both power and manual wheelchairs. Additionally, the smartphone mobile applications have differing features that separate each product. Future research is needed that compares the pressure relief tracking systems to determine the effectiveness of each device.

3.0 METHODS

In this preliminary study, a single-subject A-B design is used to examine the effect of the WiSAT system on in-seat movement behavior and the feasibility of the WiSAT study's clinical protocol. The University of Pittsburgh's Institution Review Board (IRB) approved the WiSAT study. The study was initially identified as PRO18080278 under the OSIRIS (Online Submission for Institutional Reviews) portal and then University of Pittsburgh transitioned from OSIRIS to PittPRO. Under PittPRO, the study is identified as STUDY19090305.

3.1 SAMPLE

Recruitment occurred at the University of Pittsburgh through registries and wheelchair seating clinics. Inclusion criteria for the study were individuals who (1) use a wheelchair as their primary means of mobility, (2) are over the age of 18, (3) have a self-reported history of pressure ulcers on the buttocks within the past three years, (4) currently use a skin protection cushion or a skin protection/positioning cushion, and (5) own a smartphone (Android operating system 5.0 or greater, iOS operating system of 9.0 or greater).

This preliminary study involved a convenience sample of one individual who used a Quickie manual wheelchair and a VARILITE Evolution cushion. The individual was male, 60 years old, 120 pounds, and 5 feet 6 inches tall. He was diagnosed with liver failure and complications of the liver failure caused the individual to have impaired mobility and the need to use a manual wheelchair. He had used a wheelchair for the past 25 years.

3.2 INTERVENTION

The WiSAT system includes hardware and a smartphone application. The hardware consists of a force-sensing mat (Figure 1) and a data logger (Figure 2). The clear polyester Tekscan mat contains six force sensors strategically placed. Four sensors are placed in the general area where one's thighs would reside, and the last two sensors are placed near the location of the ischial tuberosities. The mats have "cut lines" to allow them to be fitted to different sized cushions. To ensure that the mat does not inhibit the cushion's performance, it is placed inside the cushion cover, under the cushion. The data logger is a 2.75" x 2.00" x 0.80" module manufactured by Gulf Coast Data Concepts and it connects to the force-sensing mat through an Amphenol connector. Depending on the space within the cushion cover, the data logger could be placed either inside or outside the cover (Figure 3). The data logger reads and stores the voltages from the force sensors. Additionally, the data logger is equipped with wireless Bluetooth transmission capabilities to communicate with the WiSAT smartphone application. To continuously use the equipment, the data logger needs to be charged. It is recommended that the logger is charged nightly. The WiSAT equipment was tested and validated both in-lab using an interface pressure map and prototypes were tested in smaller trials in the real-world (S. E. Sonenblum & Sprigle, 2018; S. Sprigle, Sonenblum, & Feng, 2019).

Figure 1. Tekscan Mat Equipped with Force Sensors

Figure 2. Data Logger Front (Left) and Back (Right)

Figure 3. Data Logger Inside Cushion (Left) and Attached to Mat (Right)

The WiSAT smartphone application, also known as the WiSAT app, allows the users to view their in-seat movement data. The mobile app currently works on iOS devices with an operating system of 9.0 or greater. When the app is initially setup, the user goes through an initialization sequence of four different postures for 30 seconds each: normal posture, forward lean, left lean, and right lean. The user completes these leans to the extent of their ability, while remaining safe. The raw data is transmitted from the data logger to the app through Bluetooth. Approximately every 20 minutes, the app processes the raw data using algorithms developed by Georgia Tech's Rehabilitation Engineering and Applied Research (REAR) Lab and in-seat movement parameters are available for display on the smartphone. Users can view their weight shifts per hour, time between weight shifts, and their activity score per hour (Figures 4 and 5). Users also have access to view their data for the week and month. A weight shift is defined by the user unloading an area of the buttocks by at least 30% for at least 15 seconds, while the activity score is defined as any movement that redistributes forces on the buttocks, such as, squirming, fidgeting, or re-positioning.

In addition to viewing their in-seat movement data, the user also has the ability to set goals for their weight shifts per hour, time between weight shifts, and activity score per hour. Based on the literature and previous studies by the REAR Lab (S. E. Sonenblum & Sprigle, 2018; Sharon E Sonenblum et al., 2016; S. Sprigle et al., 2019), the weight shift goal has a minimum of 3 weight shifts per hour. The weight shift goal can be set anywhere from 3 to 8 weight shifts per hour. One hour is the lowest time option for the max time between shifts goal. The goal options increase by 15 minutes up until 2 hours. The activity score, also known as the in-seat movement score, has a

minimum option of 50 per hour and a maximum option of 100. The goal choices increase by 10 up until the maximum score of 100. These goals can be adjusted at any time while using the app.

Figure 4. WiSAT App Daily Weight Shift Data

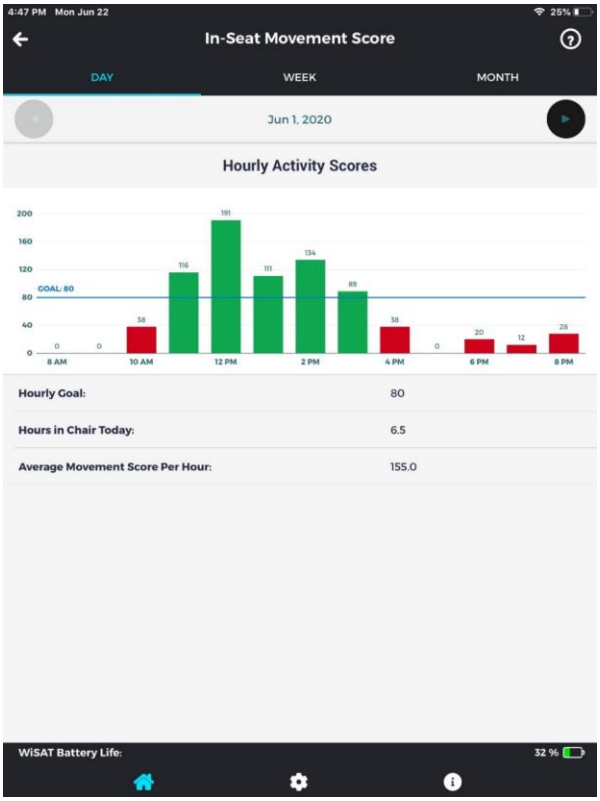

Figure 5. WiSAT App Daily Activity Score Data

3.3 STUDY PROCEDURES

The preliminary single-subject study protocol followed the WiSAT study protocol outlined in the PittPRO IRB (STUDY19090305). The protocol involved two study appointments and 5 months of use and monitoring (Figure 6). The following procedures were followed for this study.

First Study Appointment

During the initial study appointment, the participants completed an online survey, received education on pressure injuries and pressure relieving strategies, obtained instructions for the monitoring period, and got setup with the study equipment.

Use and Monitoring

The personal use and monitoring occurred over 5 months. The 5 months was divided into three different stages: 2 weeks of baseline data (no app use), 4 weeks of passive visual feedback (i.e., access app to view activity information), and about 14 weeks of passive and/or active feedback. The third stage was determined by whether the participants met their goals or not for weight shift count and activity score during the 4 weeks of passive visual feedback. If the participants met their goals, they would continue to use the passive visual feedback. However, if the participants did not meet their goals, they would be switched into active feedback for the remaining 14 weeks. If the participants were moved into the active feedback mode, they would receive notifications every 5 hours of occupancy. The notifications inform the participants which goals they are currently meeting and not meeting.

During the monitoring period, if the participants experienced any changes in their wheelchair equipment, cell phone, or pressure injury status, they were asked to report this change to the study staff.

Second Study Appointment

After the monitoring period of 5 months, the participants returned the study equipment, completed an exit interview, and completed an online survey regarding usability of the device and their beliefs on pressure injuries.

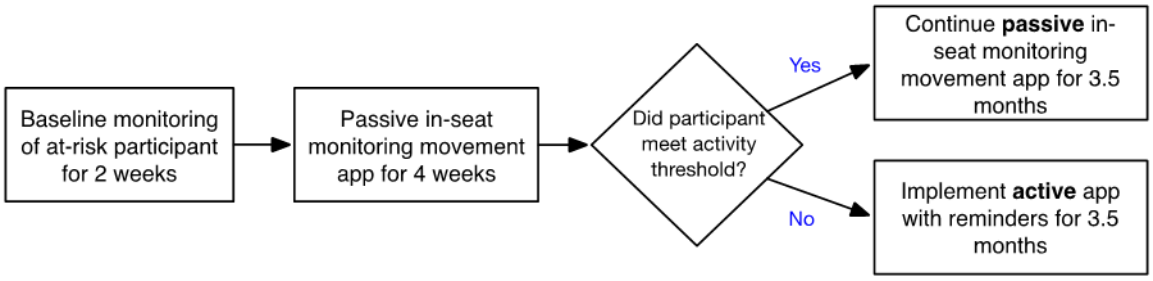

Figure 6. Flowchat of Study Partcipation Timeline

3.4 MEASUREMENT OUTCOMES AND TOOLS

3.4.1 Demographics

General demographic information, including age, sex, height, weight, occupation, current living situation, and general wheelchair use, was collected in a self-report questionnaire during the first study visit. See Appendix A for the full demographics survey. Through an interview, additional information regarding specifics on wheelchair use, such as, the use of other wheelchairs at home and make and model of the participant's wheelchair and wheelchair cushion, was collected to gain a better understanding of the participant's equipment use.

3.4.2 Pressure Ulcer Health Beliefs and Preventative Strategies

At the first study visit, the participants completed Pressure Ulcer Health Beliefs and Preventive Strategies questionnaire (Dai & Catanzaro, 1987). The questionnaire was administered before any education on pressure injuries and prevention strategies was performed to gain the participants baseline knowledge and outlook. The questionnaire measures how the participants perceive their susceptibility to pressure injuries, the severity of pressure injuries, and the usefulness of behaviors to prevent the formation of pressure injuries. (Dai & Catanzaro, 1987; Garber, Rintala, Hart, & Fuhrer, 2000). The skin care practices that were evaluated in this survey included daily skin checks, weight shifts, limit sitting time, and using a wheelchair cushion. It is re-administered during the second study appointment to assess any changes in the participants' beliefs towards pressure injuries after completing the study.

3.4.3 PROMIS Measures

The Patient-Reported Outcomes Measurement Information System (PROMIS) includes reliable and valid measures that are standardized to assess symptoms and health conditions. PROMIS utilizes computerized adaptive test (CAT) technology, after an item is answered, the next item is strategically selected from the item bank based on the previous item's response (Amtmann, Cook, Johnson, & Cella; Cella et al., 2007). Participants completed the PROMIS measures as CATs, if a CAT did not exist then the computer-based static short forms (SFs) version was completed.

During the initial study visit, five self-report PROMIS measures were administered:

- PROMIS Bank v1.0 - Self-Efficacy for Managing Chronic Conditions - Managing Medications/ Treatments, CAT – this instrument assessed one's confidence in managing medication and treatment schedules (Gruber-Baldini, Velozo, Romero, & Shulman, 2017),
- PROMIS Bank v2.0 - Upper Extremity, CAT – this instrument evaluated one's physical function in completing tasks that require the use of the upper extremities (should, arm, hand) (Kaat et al., 2019),
- PROMIS Scale v1.0 - Pain Intensity 3a, SF – this instrument measured how much someone hurts,
- PROMIS Bank v1.0 – Fatigue, CAT – this instrument assessed feelings of tiredness and exhaustion (J.-S. Lai et al., 2011), and

- Cognitive function (PROMIS Bank v2.0 - Cognitive Function, CAT) – this instrument evaluated perceived difficulties in cognitive function and thinking (J. S. Lai, Wagner, Jacobsen, & Cella, 2014).

All of the PROMIS measures were scored on a t-score (i.e., mean = 50, standard deviation = 10), where a higher score represented more of the concept being measured. These PROMIS surveys were chosen because the concepts that these surveys measure were predicted to potentially influence weight shift behavior and app use by the study team.

The PROMIS surveys have demonstrated to have content validity and construct validity when evaluated with adult members of the general population (Cella et al., 2010; DeWalt, Rothrock, Yount, & Stone, 2007). Additionally, PROMIS measures have been shown to be responsive to change when tested with a range of chronic conditions, indicating their function in clinical settings (Cook et al., 2016).

3.4.4 WiSAT App Measures

During the use and monitoring stages, the following parameters were collected by the WiSAT app and transmitted to a secure data portal.

- Activity History – raw activity score data with start and end times for each recorded "activity" movement; activity movement is defined by any movement that redistributes forces on the buttocks, such as, squirming, fidgeting, or re-positioning,
- Connection History – displays the start and end times for the phone's Bluetooth connection to the data logger,
- Device – contains information about the data logger the participant is currently using, such as, the device name, serial number,

- Error Log – this table only populates when the participant encounters an error with the WiSAT hardware or software, for example, low battery, unplugged cable, issue with algorithm, cannot read batch file,
- Goals – contains the participants' goals (date and time goal made, goal type, goal quantity) and it will re-populate each time the participants change their goals,
- Initialization Shifts – records the initialization shifts (normal posture, front lean, left lean, right lean) along with the start and end time of each shift,
- In-Seat History – displays occupancy time in 15 minute intervals; if the participant is in their wheelchair for the full 15 minutes the "duration" variable will be 15 for that entry and will continue to read 15 for the next few entries until the participant gets out of their chair,
- Month Archive – after the app has been used for a month, this table will populate with average hourly score over the month, days meeting goal over the month (for each of the three goals), and average hours in chair over the month,
- Weight Shift – raw weight shift data with start and end times for each recorded "weight shift" movement; a weight shift is defined by the user unloading an area of the buttocks by at least 30% for at least 15 seconds; this table also displays the time since previous weight shift data, and
- Scaling Factors – records the total load on the 6 sensors, the center of pressure in the anterior-posterior direction, the center pressure in the medial-lateral position, and the difference in the center of pressure compared to the upright seated position for each of the initialization shifts along with the date and time the data is recorded.

3.4.5 Usability

To assess the usability of the WiSAT system, the System Usability Scale (SUS) and a participant interview based on the SUS were completed at the second study visit (Brooke, 1996, 2013). The SUS has been shown to be a valid and reliable measure (Bangor, Kortum, & Miller, 2008; Brooke, 2013; Kirakowski, 1994). These assessments were used to evaluate the participants' experiences while using the WiSAT system. Additionally, the interview documented any issues that arose while using the equipment as well as any extenuating circumstances (e.g., travel, hospitalization) that may have disrupted the 5-month period of use and monitoring.

3.5 DATA MANAGEMENT

3.5.1 REDCap

All surveys and clinical data captured during the study visits and monitoring period were recorded in the University of Pittsburgh's Research Electronic Data Capture (REDCap). REDCap is a secure, web-based platform used to administer surveys and collect clinical trial data (Harris et al., 2019; Harris et al., 2009). There are multiple versions of REDCap available, REDCap for this project was provided by the Clinical and Translational Sciences Institute (CTSI) at the University of Pittsburgh (Grant Number UL1-TR-001857).

REDCap was primarily chosen as the clinical data collection platform due to its availability at both research sites (University of Pittsburgh and Edward Hines Jr. VA Hospital). In addition, REDCap allows for the administration of surveys and direct data entry. REDCap also has all

PROMIS survey pre-programmed in its system, allowing for easy administration and scoring of the PROMIS measures (Harris et al., 2019; Harris et al., 2009).

3.5.2 HaRI Database

The University of Pittsburgh's Health and Rehabilitation Informatics (HaRI) group created a secure research web-based database for the WiSAT study. Application Program Interface (API) endpoints allowed for communication and the transference of data between the WiSAT app and the HaRI server. Data was only transferred when the participant's phone was connected to Wi-Fi.

A participant ID, entered into the WISAT app during setup, linked the data with the participant. Data was accessed from the HaRI server through a secure web-based portal. The database contains 10 different data tables for each participant: Activity History, Connection History, Device, Error Log, Goals, Initialization Shifts, In-Seat History, Month Archive, Weight Shift, and Scaling Factors.

The HaRI database was checked daily for errors and missing data. If data did not populate within a 24-hour period, the participant was contacted. Additionally, if errors appeared in the error log, the participant was contacted.

3.5.3 MATLAB

The raw data was manipulated using MATLAB, an interactive programming environment for scientific computing, to get the data in a similar format as it was displayed to the participants in the WiSAT app. The MATLAB code output hourly and daily data on the occupancy time, number of weight shifts completed, and the activity score. The code compared the hourly data to

the hourly goal to determine if the participants met their goal for the hour. If the goal is met, the code output a “1”, while if the goal was not met, the code output a “0”. In addition, normalized data was also compared to the goal for instances when the participants did not occupy their wheelchair for the entire hour. If the participants did not spend the full hour in their wheelchair, their weight shift count and activity score was scaled based upon the amount of time the participant occupied their wheelchair for that hour and then this scaled score was compared to the goal.

The output of the MATLAB code was used to decide if the participants would receive active feedback during the final stage. On day 42 of the study, 4 weeks of using the app in passive mode, the MATLAB code was run for the participants to determine if they met their goals or not and either stay in passive feedback mode or switch into active feedback mode for the remainder of the study (~ 14 weeks).

3.6 DATA ANALYSYS

3.6.1 Analysis of the WiSAT Intervention

To examine the effect of the WiSAT system on in-seat movement, the preliminary study was analyzed as a basic A-B single-subject design. The A-B single-subject design analysis involved evaluating two dependent variables from the WiSAT system, weight shifts and activity score. Specifically, the two variables analyzed were the number of weight shift per hour averaged over the entire day and activity score per hour averaged over the entire day. Each dependent variable had a baseline period of repeated measures and an intervention period with repeated measures. The independent variable in the design was the intervention, the use of the WiSAT app

to view the in-seat movement. Typically, single-subject design data is analyzed using visual interpretation, but there's evidence that visual analysis of single-subject data can produce inaccurate and inconsistent results. This has led to the encouragement of statistical analysis along with visual interpretation of single-subject data (Nourbakhsh & Ottenbacher, 1994; Ottenbacher, 1986). For this reason, the single-subject data was analyzed using both visual interpretation and statistics.

Before any visual or statistical analyses could be completed, the data needed to be checked for serial dependency. Serial dependency, also known as autocorrelation, refers to the idea that the repeated observations taken from a single-subject will be correlated to each other; the higher the correlation between data points, the more problematic it is to use graphical analyses to analyze the data. If there is a high degree of serial dependency, changes observed through visual analyses could be due to the autocorrelation rather than the intervention. Serial dependency was measured for both phases of the data by calculating an autocorrelation coefficient for each phase. In this analysis, Bartlett's test was performed on the lag-1 autocorrelation coefficient. Bartlett's test was used to determine if the calculated lag-1 autocorrelation coefficient were statistically significant or not. If the lag-1 autocorrelation statistic was greater than $2/\sqrt{n}$, where n is the number of observations in the phase, the data were considered to be serial dependent (Ottenbacher, 1986). If serial dependency was found, only the C statistic was used to analyze the serial dependent data (Tryon, 1982). No other visual or statistical analyses are permitted to be used on serial dependent data unless the data is transformed. Data which were not serial dependent were analyzed with both visual and statistical techniques (Ottenbacher, 1986).

Visual analysis of single-subject data involved graphing the data and using the concepts of level, trend, and variability to complete the visuals inspection of the data. The concept of level

evaluates the change in magnitude of the data between the baseline and intervention phase. Level can be assessed by inspecting the actual data points, using median lines, or using mean lines to describe each phase of data. Due to no obvious extreme scores present, mean lines were used to assess level. Trend is another method to visually interpret the baseline and intervention data. To assess trend, one compares the baseline trend to the intervention trend. This trend describes the pattern of the data points; it could be linear, logistic, or even cyclic. In this case, a linear regression was used to compare the baseline and intervention phases. Lastly, variability is used to visually inspect the data. Variability, also called stability, is used to describe how different the scores are between the baseline and intervention phases. One way to visually analyze variability is through range lines. Variability can also be analyzed using other measures of spread, like standard deviation (Engel & Schutt, 2009; Ottenbacher, 1986). To analyze variability in this case, range lines and standard deviations were used.

The statistical and semi-statistical methods for interpreting single-subject design include the Tyron C statistic, the two standard deviation band method, and the split-middle method of trend estimation, also known as the celeration line. Using these statistical methods offers a quantifiable and consistent way to interpret the data. Additionally, these methods have been shown to have the ability to detect small treatment effects that may be overlooked in visual analysis (Nourbakhsh & Ottenbacher, 1994; Ottenbacher, 1986; Tryon, 1982). The complete methods used to compute these statistical analyses is described by Ottenbacher (Ottenbacher, 1986).

The two standard deviation band method was one of the semi-statistical analyses used to interpret the participant's data. An advantage of this method is that it can be completed on a small number of data points, as small as five. To compute this method, the baseline mean was calculated and plotted on a graph, extending from the baseline phase through the intervention phase. Two

additional horizontal lines are plotted, one line 2 standard deviations above the mean and one line 2 standard deviations below the mean. For the intervention phase to be significantly different from the baseline phase at the $p < .05$ level, two consecutive data points in the intervention phase must fall outside of the standard deviation bands (Ottenbacher, 1986).

Another semi-statistical method used was the celeration line method, also known as the split-middle method. The celeration line is another form of a trend line. To create the celeration line, the baseline data was initially divided in half and then the median x- and y-values were calculated for each half. The line was plotted using these median values. Fifty percent of the baseline data should fall above the trend line, and 50% of the data should fall below the trend line. The line was then extended into the intervention phase. Significance was determined using Bloom's modified probability table; the table calculated significance using a $p < .05$ level (one-tailed test). Since the intervention was predicted to cause an increase in the baseline data, the proportion of intervention data points above the celeration line was used to decide significance (Ottenbacher, 1986).

Lastly, the C statistic was calculated to determine if a significant change in performance exists across the phases. The C statistic can be applied to small data series and it can be used on data series with any degree of serially dependency. Initially, the C statistic and z-score were calculated for the baseline data to determine if there was a significant trend in the baseline data. If the baseline data were not statistically significant ($Z<1.64$), then a C statistic and z-score were computed for the combined data of baseline phase and the intervention phase. Significance was determined at the $p < .05$ level (one-tailed test) which was equivalent to a z-score more than 1.64 (Ottenbacher, 1986).

3.6.2 Analysis of Clinical Protocol

To assess the feasibility of the current protocol a single-subject was recruited and run through the clinical protocol. The subject completed all surveys and tasks described in the study procedures section.

As issues with the protocol emerged, the University of Pittsburgh team decided how to approach and solve them. Some issues that arose were strictly WiSAT hardware or software related; these were triaged directly to the Georgia Tech Team. If possible, a literature search was conducted to help resolve the issue or come-up with a possible solution. Before any changes were made to the clinical protocol, the proposed resolution was discussed by the entire study team (University of Pittsburgh, the Edward Hines Jr. VA Hospital, and Georgia Institute of Technology). After a general consensus amongst all sites was found, the change was adopted into the clinical protocol.

4.0 RESULTS

4.1 A-B SINGLE-SUBJECT ANALYSIS ON WiSAT SYSTEM

The results display the participant's data for average daily weight shifts (WS) per hour and average daily activity score (AS) per hour analyzed using a few different techniques. Fourteen days were recorded for the baseline phase and the intervention phase has thirteen days of data. Fourteen days of missing data occurs in the beginning of the intervention phase, day 15 until day 28. Data is missing in this time period due to two reasons: (1) the participant's WiSAT system stopped working on day 17 was not able to be replaced until day 29, so there is missing data from day 17 until day 28; (2) even though the WiSAT app had changed from the baseline mode to passive feedback mode, no data was able to be seen in the app on days 15 and 16. Summary statistics for the study variables, weight shifts (WS) and activity score (AS) in each phase, are displayed in Tables 1 and 2.

Table 1. Weight Shift Descriptive Statistics

Phase	Number of days	Mean (weight shifts/hr)	Standard Deviation (weight shifts/hr)	Range [min – max] (weight shifts/hr)
Baseline	14	9.3	3.2	10.8 [5.2 – 16.0]
Intervention	13	10.2	2.8	8.7 [6.1 – 14.8]

Table 2. Activity Score Descriptive Statistics

Phase	Number of days	Mean (activity score/hr)	Standard Deviation (activity score/hr)	Range [min – max] (activity score/hr)
Baseline	14	190.0	72.0	245.4 [107.5 – 352.9]
Intervention	13	157.1	48.8	136.6 [108.0 – 244.6]

For the intervention phase, it is important to note that the participant set three goals in the WiSAT app. His weight shift per hour goal was 4 weight shifts. His activity score per hour goal was 60. And lastly, his maximum time between weight shifts goal was 1 hour. His goals did not change throughout the intervention phase. Additionally, after the participant spent 4 weeks using the WiSAT app (passive feedback mode), it was determined that he was adequately meeting his goals. Therefore, he did not switch into active feedback mode, but instead he continued in passive feedback mode for the remainder of the study.

4.1.1 Serial Dependency

Serial dependency, also known as autocorrelation, was checked before any visual, semi-statistical, or statistical analysis was completed. First the baseline phase data was checked for any significant degree of auto correlation using Bartlett's test. No significant degree of auto correlation was found in the baseline phase data for either study variable (Table 3). Bartlett's test also revealed that there was no significant degree of autocorrelation when the baseline phase data and the intervention phase data were combined (Table 3). As a result, all weight shift data and all activity

score data can be interpreted using visual graphical analysis, two standard deviation band method, celeration line, and Tyron's C statistic.

Table 3. Autocorrelation Test Results for the Weight Shift and Activity Score Variables

Variable/Phase	Autocorrelation Coefficient (r)	Bartlett's Test	Autocorrelated?
WS Baseline	0.05	0.53	No
WS Intervention	0.29	0.55	No
AS Baseline	0.14	0.53	No
AS Intervention	0.27	0.55	No

Key: WS = Weight Shift, AS = Activity Score

4.1.2 Visual Analysis

Visual inspection of level, variability, and trend of the participant's average daily weight shifts per hour data is completed using Figure 7. The participant's average weight shifts per hour in the baseline phase (mean, M = 9.3 WS/hr) was lower by almost an entire weight shift per hour when compared to the average in the intervention phase (M = 10.2 WS/hr). Additionally, based on visual analysis, range, and standard deviation, there was a higher degree of variability in the baseline phase (Range, R = 10.8 WS/hr, standard deviation, SD = 3.2 WS/hr) of the participant's weight shift data when compared to intervention phase (R = 8.7 WS/hr, SD = 2.8 WS/hr). This indicated that the spread of the data is more compact in the intervention phase then in the baseline phase. Lastly, the baseline phase (slope = -0.16 [WS/hr]/day) and intervention phase (slope = -0.21 [WS/hr]/day) had similar trends, both exhibit a slight negative trend.

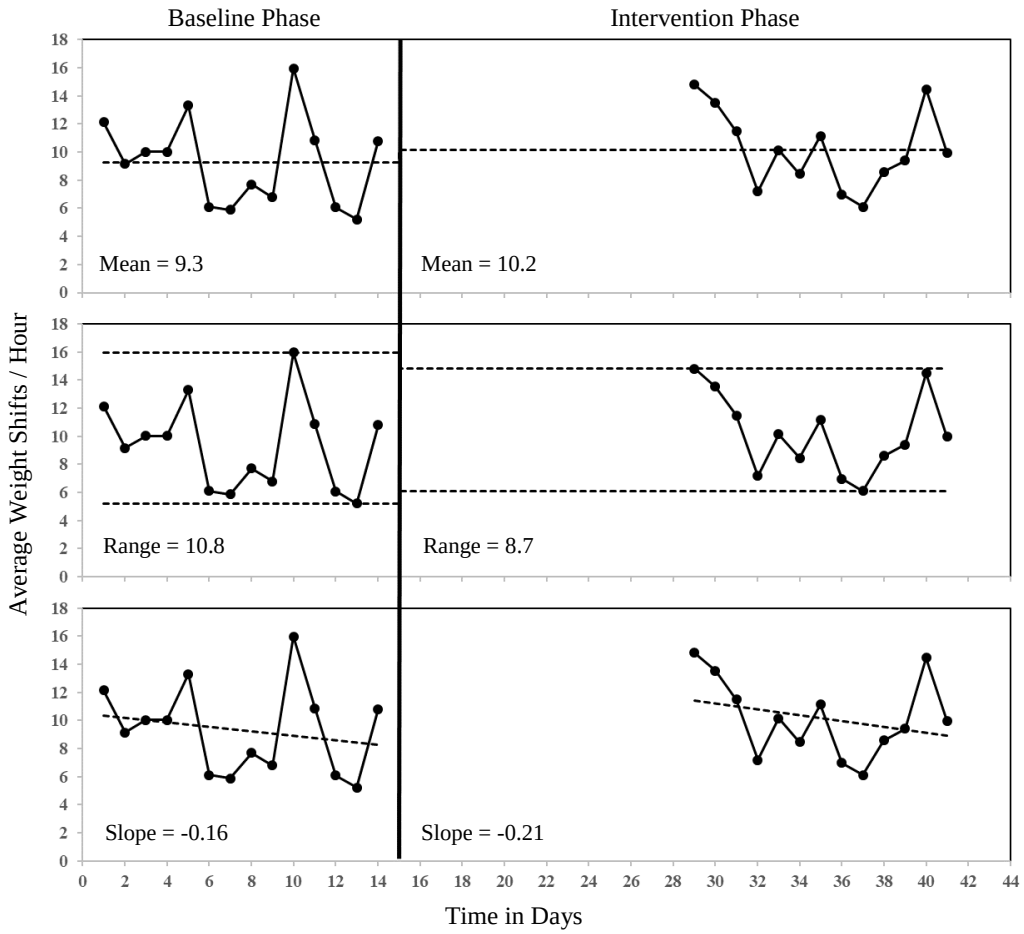

Figure 7. Weight Shift Level, Variability, and Trend Analysis

Visual inspection of level, variability, and trend of the participant's daily activity score data is completed using Figure 8. The participant's average measure of activity score per hour in the baseline phase (M = 190.0 AS/hr) was higher by approximately 30 points per hour compared to the average in the intervention phase (M = 157.1 AS/hr). Additionally, based on visual analysis, range, and standard deviation, there was a higher degree of variability in the baseline phase (R = 245.4 AS/hr, SD = 72.0 AS/hr) of the participant's activity score data when compared to intervention phase (R = 136.6 AS/hr, SD = 48.8 AS/hr). The ranges had a difference of over 100 movements per hour between the two phases. Like the weight shift variable, this indicated that the

spread of the data is more compact in the intervention phase then in the baseline phase. Lastly, the baseline phase (slope = -2.41 [AS/hr]/day) and intervention phase (slope = 6.19 [AS/hr]/day) exhibit different trends over the phases. The baseline data had a negative trend over the phase and the intervention data demonstrated a positive trend.

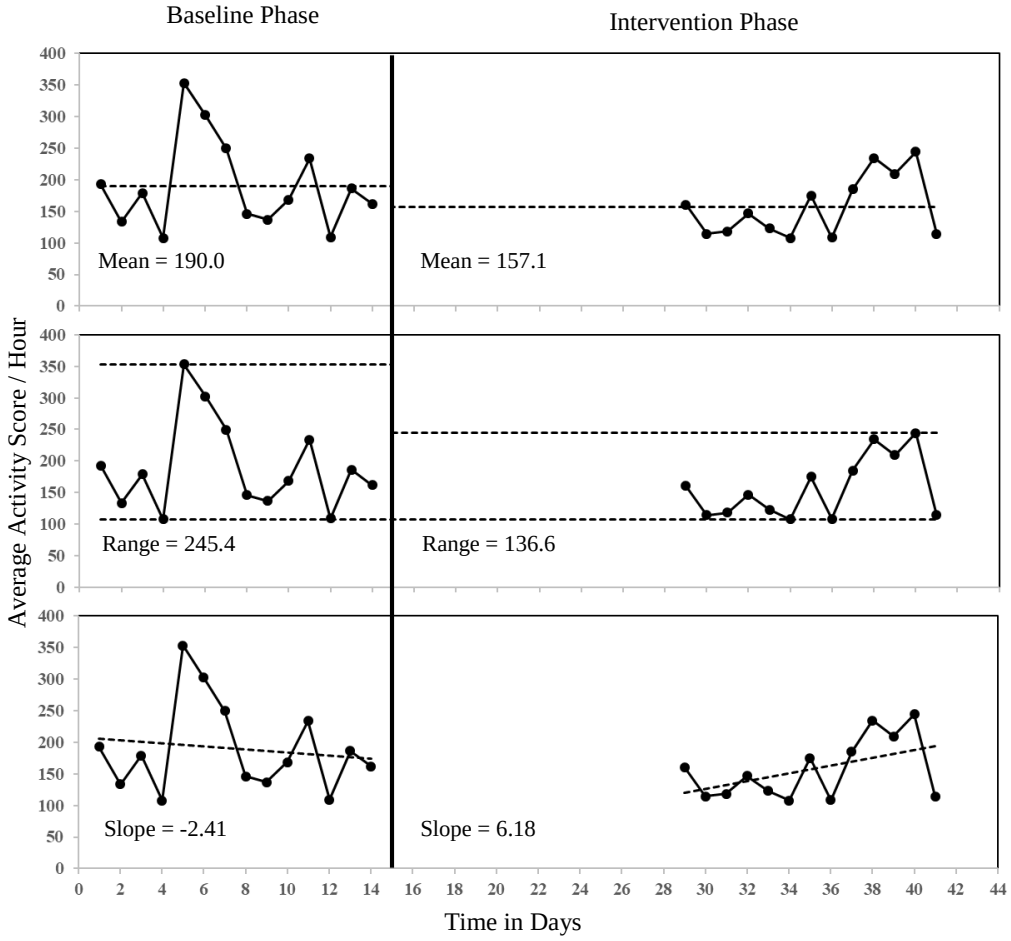

Figure 8. Activity Score Level, Variability, and Trend Analysis

4.1.3 Semi-statistical and Statistical Analysis

Two semi-statistical analyses, two standard deviation band method and celeration line, and one statistical analysis, Tyron's C statistic, were completed on the weight shift and activity score data for the participant. Table 4 summarizes the results of these analyses. The two standard

deviation band method showed no significant effect for neither the weight shift data (Figure 9) nor the activity score data (Figure 10). No scores in the intervention phase fell outside of the standard deviation bands for either variable. For the celeration line analysis, all intervention phase observations were above the celeration line for both the weight shift variable (Figure 11) and activity score variable (Figure 12). According to the Bloom probability table, this proportion of data points above the line indicate that the intervention had a significant effect. However, due to missing data at the start of the intervention phase, it is difficult to determine if this assessment is accurate.

Lastly, the C statistic was used on the baseline phase data to assess the trend and then on the combined data to assess if a significant change in performance exists across phases for the daily weight shift averages and daily activity score averages. Based on the C statistics calculated for the weight shift baseline data (z-score, $Z = 0.35$) and activity score baseline data ($Z = 0.60$), the baseline data exhibited no significant trend ($Z < 1.64$). As a result, a C statistic could be calculated for the combined baseline and intervention phases for both variables. For the weight shift data, the C statistic analysis on the combined data indicated that there was no significant difference at the $p < .05$ level ($Z < 1.64$) in the weight shift data ($Z = 1.09$) between the baseline phase and intervention phase. Similarly, for the activity score data, the C statistic analysis on the combined data indicated that there was no significant difference at the $p < .05$ level ($Z < 1.64$) in the activity score data ($Z = 1.36$) between the baseline phase and intervention phase.

Table 4. Summary of Single-Subject Statistical Anlysis Results

Variable	2 SD Band Method Significance*	Celeration Line Significance*	Tyron's C Statistics		
			Z_A	Z_{AB}	Significance*
Weight Shift	No	Yes	0.35	1.09	No
Activity Score	No	Yes	0.60	1.36	No

*Significance at p< .05 level

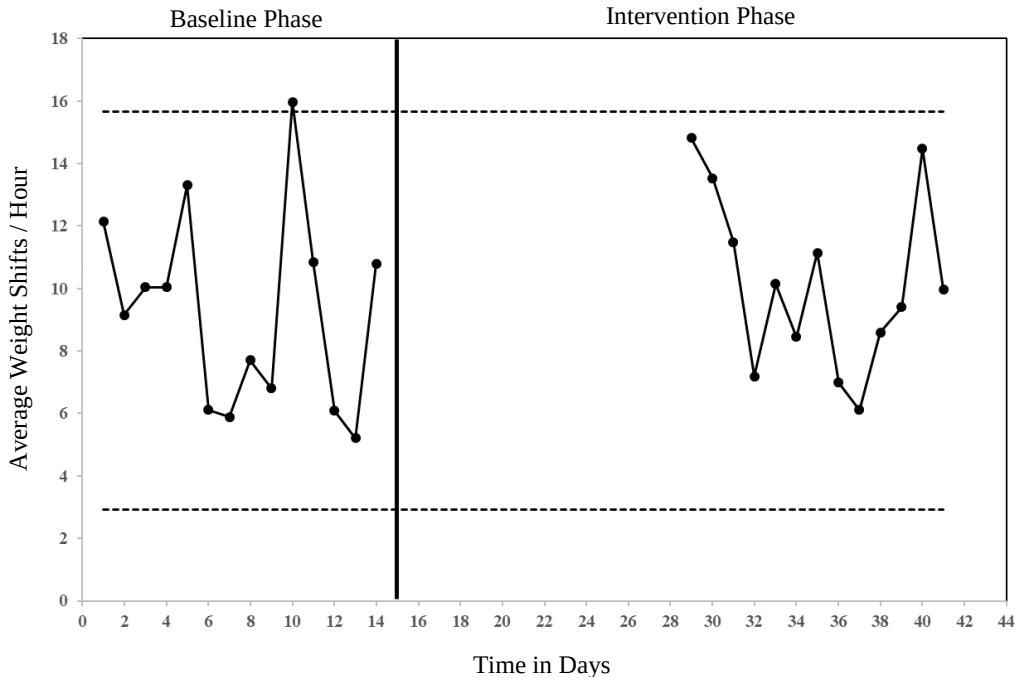

Figure 9. Weight Shift Two Standard Deviation Band Method

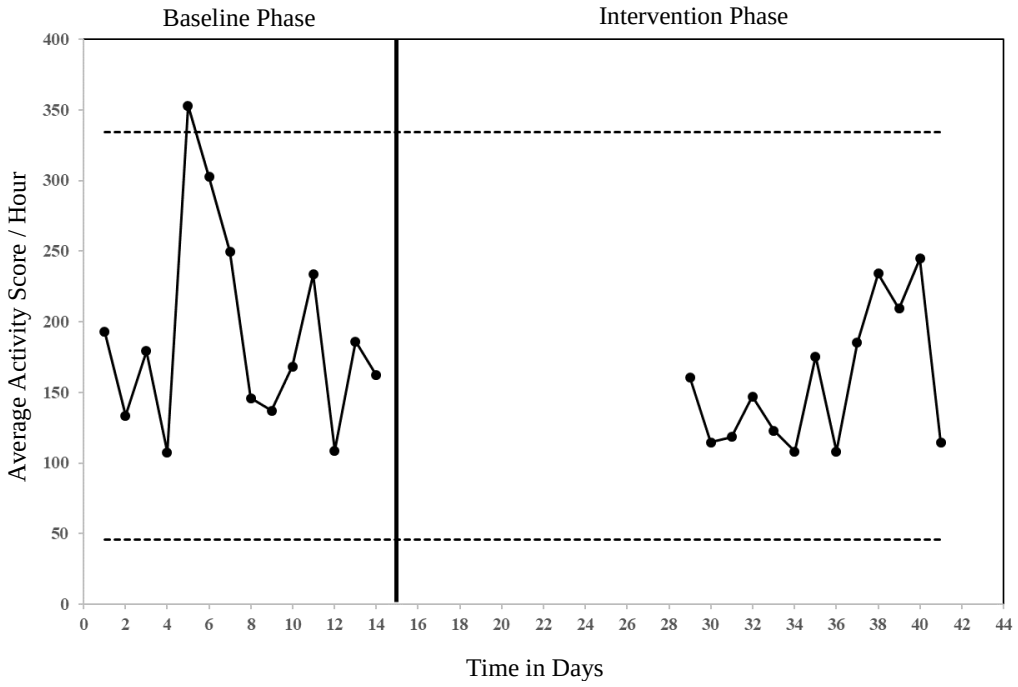

Figure 10. Activty Score Two Standard Deviation Band Method

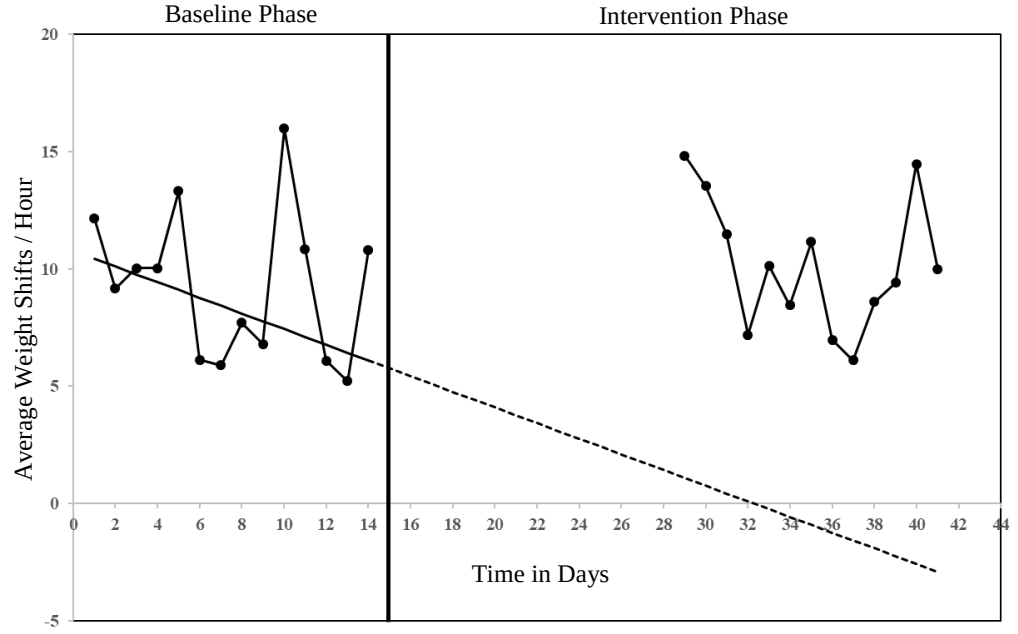

Figure 11. Weight Shift Celeration Line

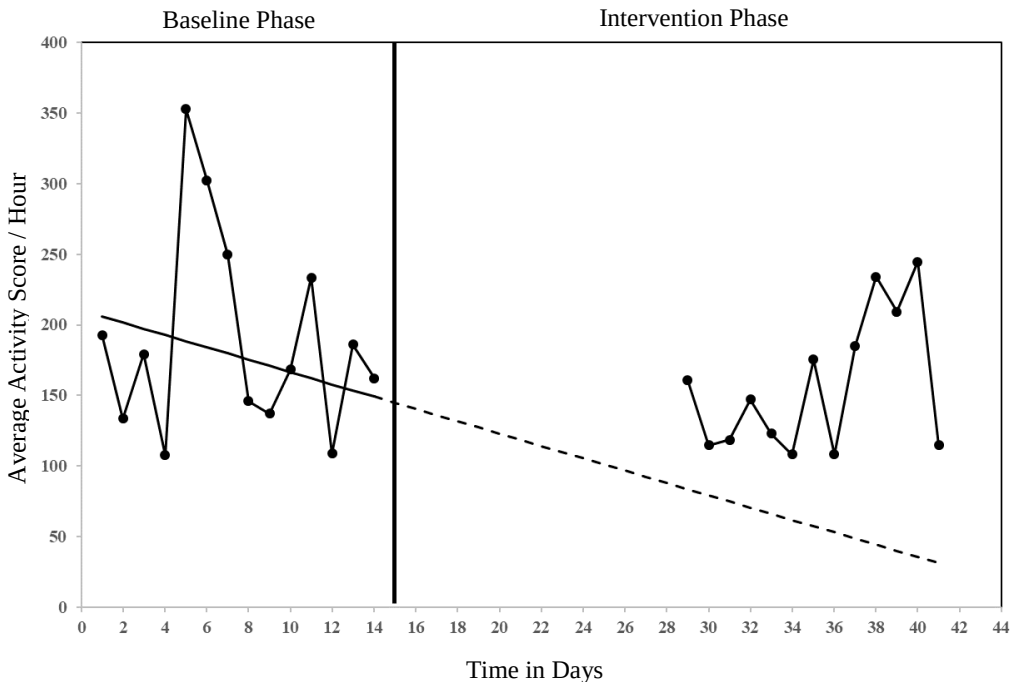

Figure 12. Activity Score Celeration Line

4.2 SURVEY RESULTS

Surveys responses were recorded in REDCap during both the first study visit (baseline) and the second study visit (post –intervention). Tables 5, 6, and 7 display these survey results.

4.2.1 PROMIS Results

Five PROMIS surveys were administered during the baseline visit. The t-scores for each of the PROMIS surveys are displayed in Table 5. The raw scores from each instrument have been rescaled into t-scores. The t-scores are standardized scores with a mean of 50 (average score of the

United States general population) and a standard deviation of 10. Therefore, a score above 50 indicates that the participant experiences that concept more than average.

The participant's standard scores were above 50 for two of the concepts measured. The participant is more than one standard deviation above the mean for the self-efficacy measure (t-score = 62.8). This indicates that the participant has greater self-efficacy for managing medications and treatments then the general chronic condition population. The participant is about a half of a standard deviation above the general population's mean of 50 for cognitive function (t-score = 56.6), implying that the participant's cognitive function and thinking is better than the average person.

On the remaining PROMIS measures, the participant's t-scores were below the general population's mean of 50; all of these concepts were within one standard deviation of the mean. These scores demonstrated that the participant experiences worse pain intensity (t-score = 42.6), fatigue (t-score = 45), and upper extremity function (t-score =42.7) than the general population.

Table 5. PROMIS Scores

Measure	T-score
Self-Efficacy	62.8*
Upper Extremity Function	42.7
Pain Intensity	42.6
Fatigue	45
Cognitive Function	56.6*

*Measures the concept more than the general population if score is above 50

4.2.2 Pressure Ulcer Health Beliefs and Preventative Strategies Results

This survey was administered twice, at the first (baseline) and the second (post-intervention) visit (Table 6). The baseline response demonstrates that the participant believes that pressure ulcers are serious, that he is somewhat at-risk for developing them, and that there are ways to prevent himself from developing a pressure ulcer.

Five months after the baseline visit and using the WiSAT system the participant retook the Pressure Ulcer Health Beliefs and Preventative Strategies Survey. In comparing the baseline responses to the post-intervention responses, all of the responses remained the same except the answer to the question “How likely do you believe you are to get pressure ulcers?”. His response changed from “somewhat likely” to “not very likely” (see Table 6).

Table 6. Pressure Ulcer Health Beliefs and Preventive Strategies Survey Responses

Questions	Response Choices	Baseline Response	Post-intervention Response
How serious do you believe a pressure ulcer would be for you if you were to get one in the future?	Not serious, Fairly serious, Very serious, Life threatening	Very serious	Very serious
How likely do you believe you are to get pressure ulcers?	Very likely, Somewhat likely, Not very likely	Somewhat likely	Not very likely
How much do you believe pressure ulcers would interfere with your daily activities?	None, Some, A lot	A lot	A lot
How difficult do you believe pressure ulcers are to treat?	Easy to treat, Difficult to treat, Not treatable	Difficult to treat	Difficult to treat
To what degree do you believe that you can prevent your getting pressure ulcers?	Completely, Somewhat, Not at all	Completely	Completely
To what degree do you believe that the following practices make a difference in your chances of getting pressure ulcers?			
Daily skin checks	None, Some, A lot	Some	Some
Weight shifts	None, Some, A lot	A lot	A lot
Limit sitting time	None, Some, A lot	A lot	A lot
Using a wheelchair cushion	None, Some, A lot	A lot	A lot

4.2.3 Usability Results

The results of the system usability scale regarding the participant's experience with the WiSAT system is in Table 7. The raw scores are converted to a scaled score between 0 to 100, where 100 indicates a product or system with "better" usability. The single participant resulted in a scaled score of 42.5 when evaluating WiSAT. There is not a clear standard method of interpreting the SUS in the literature, however, a few researchers have used the "university grade analog" and attempted to validate this method. Under this method, scores of 90 to 100 are consider an A, 80 to 89 are a B, and so on (Bangor et al., 2008). By this definition, the score of 42.5 would be considered an "F".

Although the participant's SUS score is on the lower end of the spectrum, the participant had numerous issues with the WiSAT system over the 5-month period and this was apparent in the usability exit interview. During the interview he mentioned numerous hardware and software issues that he encountered. A lot of these issues are described in section 4.3, "Protocol Issues".

Table 7. System Usability Scale Score

Measure	Score
System Usability Scale	42.5

4.3 PROTOCOL ISSUES

4.3.1 Recruitment

Recruitment started off slower than expected for a few reasons. Recruitment was initially restricted to iOS (iPhone) devices and manual wheelchair users due to limitations of the WiSAT equipment. The WiSAT app was being developed on two phone platforms, iOS and Android. The iOS app development progressed a lot faster than the Android version. The iOS app was deployed in late-December of 2019 and as of June of 2020 there still is no timeline for the Android app deployment. In addition, thorough testing of the WiSAT equipment had not yet been performed with the use of power seating. Power wheelchair users who are unable to physically perform functional weight shifts and pressure reliefs themselves, often have power seat functions, such as tilt and recline, to help with pressure reliefs and weight shifts (Lange & Minkel, 2017). Since the WiSAT system is still undergoing reliability testing for measuring weight shifts performed with power seat functions, power wheelchair users were omitted from recruitment for an unknown period of time.

Over a few months' time period, the research staff screened 12 potential participants. From the first 12 individuals screened, only five were eligible under the current inclusion criteria. Out of the five qualified individuals, three individuals had iOS (iPhone) devices and one of the eligible iPhone users was also a power wheelchair user. This resulted in only two people who could currently participate from a few months of screening.

Since the equipment and app development problems had no known resolution date, the research team explored the reasons why the other seven individuals were not eligible. The main reason the seven individuals were deemed to not qualify for the study was due to the inclusion

criteria assessing the individuals' risk for developing pressure injuries. To be considered for being at risk of developing pressure injuries, individuals were required to have a history of pressure injuries on their buttocks in the past three years AND a variation of a skin protection cushion. Individuals did not meet these criteria for a few different reasons which included: the most recent pressure injury occurred more than 3 years ago, the individual used a skin protection cushion but had no history of pressure injuries on the buttocks, and the individual's cushion make and model were unknown so it could not be determined if the individual used a skin protection cushion. Upon further reflection of the inclusion criteria for being at risk for pressure injuries, it appeared that the current criteria may be too restrictive.

A literature review was conducted on how to classify a wheelchair user's risk for pressure injuries. There are many intrinsic and extrinsic factors that affect individuals' risks for developing pressure injury including previous skin breakdown, nutrition, poor hygiene, excess moisture, loss of muscle mass, aging, dry skin, over- or underweight, loss of sensation, and limited mobility (Consortium for Spinal Cord Medicine Clinical Practice Guidelines, 2014; European Pressure Ulcer Advisory Panel et al., 2019). There are standardized instruments used to quantify these risks. The Braden Scale, Waterlow, Norton Scale, and the Spinal Cord Injury Prevention Pressure Ulcer Scale are the standardized tools most commonly used to assess risk of pressure injury development (Braden, 1998; Consortium for Spinal Cord Medicine Clinical Practice Guidelines, 2014; Lange & Minkel, 2017; Norton, McLaren, & Exton-Smith, 1962; Waterlow, 2005). All four of these tools are typically administered by clinicians and used in conjunction with clinical judgment while completing them. The Braden Scale, Waterlow, and Norton Scale are for the general population, while the Spinal Cord Injury Prevention Pressure Ulcer Scale is intended for individuals with

spinal cord injury. Since this study's inclusion and exclusion criteria do not address diagnosis, only the tools applicable to the general population were reviewed (Table 8).

Table 8. Pressure Injury Risk Assessment Tools

Instrument	Components	Scoring
Braden Scale (Braden, 1998)	Six subscales: • sensory perception • moisture • activity • mobility • nutrition • friction and shear	Each subscale is rated on a scale of 1 to 4, where 1 indicates highest risk and 4 indicates lowest risk. The subscale scores are summed and the total score can range from 6 to 23. • Very high risk: score of 9 and below • High risk: score of 10 to 12 • Moderate risk: score of 13 to 14 • Low risk: score of 15 to 18 • No risk: score of 19 to 23
Waterlow (Waterlow, 2005)	Seven main items/sections: • build/weight • height • visual assessment of skin • sex/age • continence • mobility • appetite Special risk factors: • tissue malnutrition • neurological deficit • major surgery/trauma • medication	Each section score is summed and compared to the following risk categories: • 10+ At Risk • 15+ High Risk • 20+ Very High Risk
Norton Scale (Norton et al., 1962)	Five domains: • activity • mobility • incontinence • physical condition • mental health condition	Each domain's scale is added together to form a total scale that ranges from 5-20. A lower total score indicated a higher level of risk for developing a pressure injury. Generally, the risk factors are coded as: • Low risk: Greater than 18 • Medium risk: score of 18 to 14 • High risk: score of 14 to 10 • Very high risk: less than 10

Interrater reliability has been assessed in all 3 of these standardized scales. The Braden Scale and Norton Scale have demonstrated the most positive results in terms of interrater reliability, numerous studies have found that the Waterlow tool has poor interrater reliability (Charalambous, Koulori, Vasilopoulos, & Roupa, 2018; Ek & Bjurulf, 1987; Walsh & Dempsey, 2011; Wang et al., 2015). Additionally, all of these assessments are meant to be completed along with clinical judgment. Some of the tools rely on more clinical input than the others. For example, Waterlow contains a section in which a visual analysis of the skin is completed and the Norton scale lists 5 sections names without much description on how to rate the sections (ex. physical condition: good [4], fair [3], poor [2], very bad [1]) (Norton et al., 1962; Waterlow, 2005). While the Braden scale has detailed descriptions for each subscale (Braden, 1998).

In addition, in researching the scales further, it was discovered that the Braden Scale subscales have been reviewed independent of the entire scale (Alderden et al., 2017; Bergquist, 2001; Gadd, 2014; Gadd & Morris, 2014; Lim, Mordiffi, Chew, & Lopez, 2019; Sardo, Guedes, Alvarelhão, Machado, & Melo, 2018; Tescher, Branda, O'Byrne, & Naessens, 2012; Zambonato, de Assis, & Beghetto, 2013). The subscales have demonstrated to be predictive of pressure injuries both within and outside of the complete scale (Alderden et al., 2017; Gadd, 2014; Gadd & Morris, 2014; Sardo et al., 2018; Tescher et al., 2012; Zambonato et al., 2013). Some studies have found that focusing on the subscales can aid with prevention planning based on risk factors specific to the participants (Gadd, 2014; Gadd & Morris, 2014; Tescher et al., 2012). Similar findings were not found pertaining to the Norton Scale's domains or Waterlow's sections.

Overall, from the literature review on tools used to classify risk for pressure injuries, it appeared that the Braden Scale would be the most valuable for the WiSAT study. Although all of the aforementioned tools are meant to be used along with clinical judgment, the Braden Scale more

clearly defines its classifications and categories. Furthermore, the Braden Scale's subscales have been proven to be clinically relevant independent of the full scale which may be useful in screening individuals for study eligibility.

4.3.2 Data Collection and Equipment

During the study participant's trial of the clinical protocol, he experienced a few problems with the WiSAT equipment. Most of these issues impacted data collection and resulted in missing data. The problems included both software issues (WiSAT app) and hardware issues (WiSAT data logger and accessories). The problems and their impacts are discussed in Table 9.

Table 9. Data Collection Problems

Issue Type	Issue	Impact
Software	When the WiSAT app was downloaded over cellular data, the app could not recognize when the phone was connected to Wi-Fi.	Data was not transferred to the HaRI data portal. Data is only transferred when the app is connected to Wi-Fi and the app was unable to recognize when the phone was connected to Wi-Fi.
Hardware	On three separate occasions, the participant was no longer able to charge the WiSAT data logger with the inductive charger due to a weakened connection between the micro-USB and the inductive charger.	Charger needed to be replaced each time this occurred. On one occasion this caused the logger to completely run out of battery, leading to missing data.
Hardware	When all battery is drained out of the data logger, the logger's internal clock resets to January 1, 2007.	The data logger will no longer collect the participant's data.
Software	An "Add Occupancy Algorithm Exception" causes over 100,000 errors a day.	The HaRI data portal is overloaded and does not allow one to access the "Error Log". Participant data is no longer transferred to the HaRI portal and the participant must exit the app.

4.3.3 Active-Passive Decision

After using the WiSAT app for 4 weeks in passive visual feedback (day 42 of the home trial period), the research team must determine the participants' feedback type for the third stage of the field trial period. The third stage is decided by examining the participants' data from the 4 weeks of passive visual feedback and determining whether the participants met their goals or not during the 4 weeks. If the participants met their goals, they would continue to use the passive visual feedback; however, if the participants did not meet their goals, they would be switched into active feedback for the remaining time in the study. Active feedback involves notifications being sent to the participant's phone after 5 hours of occupancy time. The notification informs that participants whether or not they have been reaching their goals over the past five hours of occupying their wheelchair.

In theory this sounds simple, the participant moves into active feedback if they are not meeting their goals or the participant remains in passive feedback if they are meeting their goals. But how does the research team define "meeting goals"? Each hour the participant has three goals they are working towards- weight shift count, activity score, and time between shifts. Do they need to meet all three of these goals every hour for the entire four-week period in order to remain in passive feedback? Also, the participants can change their goals at any time during the four-week period, how does that affect the definition for "meeting goals"?

A literature search was conducted on how to define "meeting goals", but there was a lack of literature related to this decision. To help make this decision, the research team examined literature on weight shift frequency as well as analyzed weight shift frequency data from four participants (Figure 13 and Table 10), the case study from the University of Pittsburgh and three other participants from Georgia Tech.

In the review of the current literature on sitting behavior and weight shift frequency of wheelchair users, very few articles were found. The majority of the literature found was written by the developers of the WiSAT system, the REAR lab team. In one study of 17 individuals with spinal cord injury (SCI), subjects averaged about 1 pressure relief every 2 hours, where a pressure relief is defined as a weight shift in which the participant unloads their wheelchair cushion by 90% or more for 15 - 120 seconds, and 2 to 3 weight shifts every hour (S. Sprigle et al., 2019). In another study two groups of individuals with SCI, one with a recurrent history of pressure injuries (n = 12) and one without a recurrent history of pressure injuries (n=17), were assessed. This study demonstrated that weight shifts were performed more often by the individuals without a recurrent history of pressure injuries. About 2.5 weight shifts per hour (median) were performed by the groups without a history and only 1 weight shift per hour (median) was performed by the group with a history. Pressure reliefs, defined in the same manner as the first study, were performed less than once every 3 hours for both groups (S. E. Sonenblum & Sprigle, 2018). The last study was conducted with 28 manual wheelchair users with a history of an SCI. This cohort of participants performed weight shifts about 2.4 times per hours on average and less than one pressure relief every hour (Sharon E Sonenblum et al., 2016).

To further analyze in-seat behavior, four participants' data is presented in Figure 13 and Table 10. All four participants were male, manual wheelchair users. The three participants from Georgia Tech (GTech1, GTech2, and GTech3) were diagnosed with a form of spinal cord damage. GTech1 was diagnosed with a C5 level, incomplete injury and he used a Quickie wheelchair with a Jay Basic cushion. GTech2 was diagnosed with a T10 level, complete injury and he used a TiLite AeroZ wheelchair with a Jay Fusion cushion. GTech3 was diagnosed with hereditary spastic paraplegia and he used a Ki Mobility Rogue wheelchair with a Jay Union cushion. Lastly, the

Pittsburgh participant, Pitt1, was diagnosed with liver failure. Complications of the liver failure caused the individual to have impaired mobility and the need to use a manual wheelchair. Pitt1 used a Quickie wheelchair and a VARILITE Evolution cushion.

All four participants spent varying lengths of time using the WiSAT equipment. This data was collected only using the WiSAT hardware (sensor mat and logger), the participants did not have access to viewing any data in the app or to setting goals in the app while collecting this data. The weight shift count was recorded every hour, for the hours in which the participant did not spend a full 60 minutes on their wheelchair cushion, the weight shift frequency was normalized (weight shift count/ fraction of the hour spent on the wheelchair cushion). The average hourly weight shift count was calculated for each day (Figure 13), the participants' hourly weight shift counts ranged from 1.3 weight shifts per hour to 11.3 weight shifts per hour. Table 10 displays the summary statistics of the participants' data.

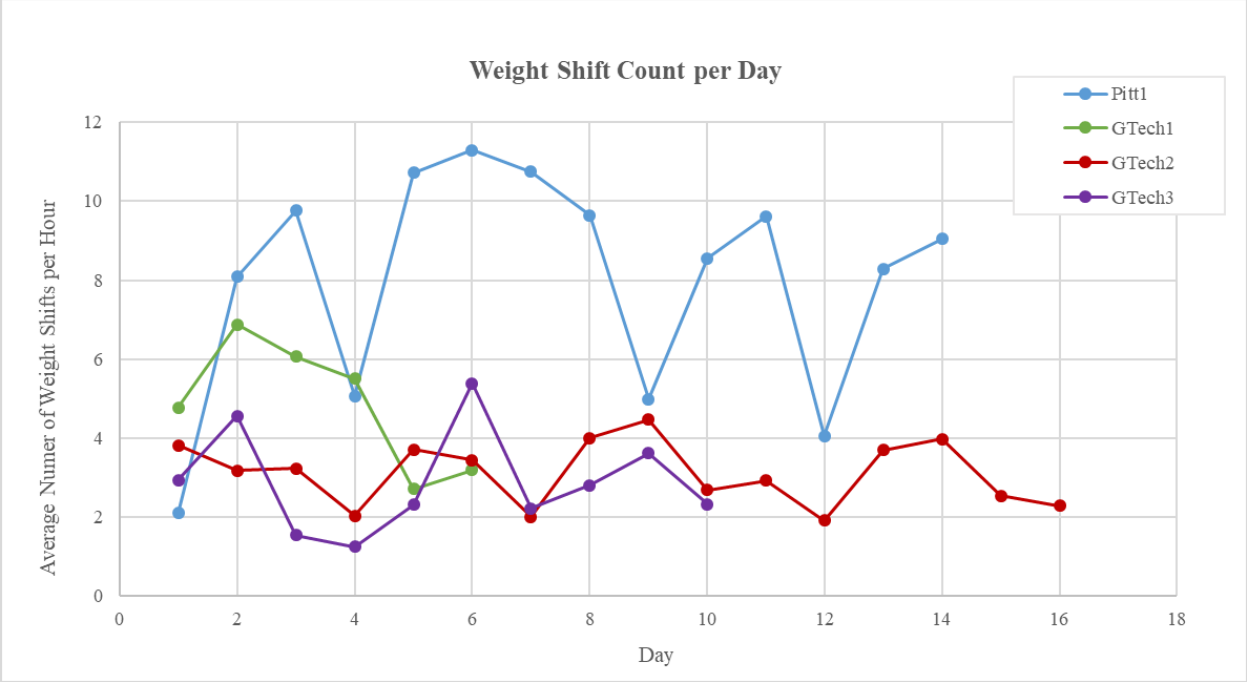

Figure 13. Graph of Hourly Weight Shift Count per Day

Table 10. Weight Shift Count Summary Statistics

Participant	Number of Days	Average Occupancy per Day (hr)	Number of Weight Shifts per Hour	
			Mean (SD)	Range [min – max]
Pitt1	14	7.6	8.0 (2.8)	9.2 [2.1 – 11.3]
GTech1	6	10.2	4.9 (1.6)	4.2 [2.7 – 6.9]
GTech2	16	13.9	3.1 (0.8)	2.6 [1.9 – 4.5]
GTech3	10	6.8	2.9 (1.3)	4.1 [1.3 – 5.4]

5.0 DISCUSSION

5.1 EFFECT OF THE WiSAT SYSTEM

The single-subject design analysis involved examining two outcome variables of the WiSAT system, weight shift and activity score. The data examined came from a single participant and was evaluated using both visual inspection along with statistical and semi-statistical methods. Visual analysis tends to be considered more subjective while the computational analyses are considered to be more objective. As with most single-subject design analyses, the conclusions drawn from this analysis cannot be generalized to the greater population due to the small sample size (Nourbakhsh & Ottenbacher, 1994; Ottenbacher, 1986). The conclusions are important for interpreting the response pattern or trend of the intervention.

The visual inspection analysis evaluated changes in level, variability, and trend between the baseline phase and intervention phase (Figure 7 and Figure 8). All three of these assessments were used to assess different aspects of the data to detect an overall visual change between the phases. The analysis demonstrated an increase in mean, a form of level analysis, for the weight shift data and a decrease in mean for the activity score data in the intervention phase. The intervention phase weight shift data increased by almost a full weight shift (difference of 0.9) when compared to the baseline phase data. This change could indicate that the WiSAT system may have had influence over the participant's weight shift behavior. Conversely, the activity score mean dropped between phases by about 30 points. Since the participant daily activity scores averages meet and exceed the maximum goal setting in the WiSAT app for all days in both phases, this change in level may not be as influential as the weight shift change. On the other hand, this change

in level could be a consequence of the increased weight shift numbers seen in the intervention phase. The participants increased focus on weight shift count may have naturally led to a decrease in the participant's activity scores. Additionally, level is typically assessed by observing the pattern that occurs immediately switching from the baseline phase to the intervention phase (Ottenbacher, 1986); however, this could not be evaluated due to missing data for both outcome variables.

The analysis showed decreased variability in the intervention phase for both outcome variables. Both the ranges and standard deviations demonstrated similar decreasing trends. This change in variability for both variables could be related to the participant's ability to view his in-seat data in the WiSAT app.

Lastly for the visual analysis, trend was examined in both phases. A change in trend is generally categorized as a change in direction of the data pattern (Ottenbacher, 1986). For weight shift data, the general trend lines both demonstrate decelerating trend. The slopes are both negative and have nearly equivalent magnitudes. On the other hand, the activity score data demonstrates a change in trend. After the introduction of the intervention, the activity score data's decelerating trend changed to an accelerating trend. This change in trend is indicative of the potential influence of the WiSAT app had on the participant's activity levels.

The data was also interpreted using a more objective approach. The computation analyses are summarized in Table 4. Both the two standard deviation band method and Tyron's C statistic did not indicate a significant difference between the baseline and the intervention data. However, the celeration line method did exhibit a significant result. Since the celeration line method involves extending the celeration line into the intervention phase, the missing data in the intervention phase may have impacted the significance conclusion. Due to the occurrence of the missing data and its

unknown effect, the validity of the significant results is in question. The missing data does not impact the other two computation analyses.

The three computational tests did not agree with each other. As mentioned the celeration line method produced statistically significant results, while the other two methods did not. Based on the literature, there is an overall low percentage of agreement between the three tests. However, it is quite common for the two standard deviation band method and the C statistic to agree, which was seen in this analysis. In a study conducted by Noubakhsh and Ottenbacher, all three computational methods agreed 38% of the time, while the two standard deviation band method and C statistic agreed 71% of the time. The two standard deviation band method only agreed 48% of the time with the celeration line method (Nourbakhsh & Ottenbacher, 1994). Although it is common for the celeration line method to not agree with the other two methods, this analysis demonstrated a further need of exploring the WiSAT system with more subjects.

There were mixed results from conducting both the statistical and visual analyses. From reviewing the literature, it is somewhat typical for the visual analysis to agree with the statistical analysis (Bobrovitz & Ottenbacher, 1998). However, this is not always the case. As such, it was important to conduct both types of analyses. In addition, different analyses can reveal potential treatment effects that were not seen with the other forms of analysis. Visual analysis allows one to observe major treatment effects and look at the process as well as the outcome. In evaluating the process and the data over time, researchers may observe other interesting visual aspects of the treatment through graphical analysis that would not be seen through the computational analysis. For example, it was noticed that the app may have cause a decrease in variability in the intervention phase which would have been unknown if only statistical methods were used. On the other hand, statistical analyses are useful for detecting small treatment effects previously missed in the visual

interpretation (Ottenbacher, 1986). They are also useful for producing consistent results across multiple raters, which is not always the case with visual analyses (Kinugasa, Cerin, & Hooper, 2004; Ottenbacher, 1986). Another advantage of statistical analyses is that there are some methods that can be used on serial dependent data. Visual analysis cannot be conducted on serial dependent data while the Tyron C statistic can be used to analyze serial dependent data (Nourbakhsh & Ottenbacher, 1994; Ottenbacher, 1986). Overall, the single-subject analyses demonstrated that the app may be influencing the participant's behavior, but more subjects are needed to establish the WiSAT system's impact. Changes in the visual analyses demonstrated the intervention's potential effect. The standard deviation band method and the C statistic did not reveal any significant changes between the baseline and intervention phases, but the celeration line method revealed a potential significant change that should be further explored with a full data set.

5.2 SURVEYS

5.2.1 PROMIS Measures

Based on the participants results on the PROMIS measures, it is apparent that the participant experiences more pain and fatigue as well as lower upper extremity functionality (should, arm, hand) than the general population. All of these factors may impact the participant's ability and complete functional weight shifts. These factors may also influence the participants use of the WiSAT system, primarily his interactions with the WiSAT app.

In addition, the participant exhibited above average cognitive function and above average self-efficacy for managing his medication and treatments. These two elements could have an

impact on a participant's ability to adhere to the weight shift clinical guidelines. In this case, the participant's above average self-efficacy is corroborated by the participant's performance in the study. The participant's daily average number of weight shifts per hour met and exceeded the clinical minimum of 3 weight shifts per hour each day (Figure 7). Additionally, as later discussed, the participant also met his goals more than 80% of the time. Future participants' performances on both of these measures, cognitive function and self-efficacy, may predict their ability to meet and reach their goals. In order to draw influential conclusions from these PROMIS measures a greater sample size is needed.

5.2.2 Pressure Ulcer Health Beliefs and Preventative Strategies

The participant's beliefs towards pressure ulcers and preventative strategies did not change much over the course of the study based on the pre- and post- survey results (Table 6). As mentioned, all responses to the survey remained the same except his response to the question "How likely do you believe you are to get pressure ulcers?". His answer changed from "somewhat likely" to "not very likely". It is unknown why this change occurred, but it could be a result of being able to view his data on the app and noticing how much he was actually moving throughout the day. The participant was almost always above the minimum weight shift number of 3, so there is a chance that this influenced his thoughts on his own risk for developing a pressure injury.

5.2.3 Usability

Although the participant's score on the SUS is lower than expected (score = 42.5), this could be primarily attributed to all of the issues that the participant encountered during his trial. In

the preliminary study, the study team hoped to iron out issues with the protocol and major issues with the equipment to ensure minimal interruptions and problems with future participants. As a result, we expected this participant's experience with the equipment to be less than ideal; this was reflected in both the SUS and the participant's interview responses. Since the issues experienced by this participant have been resolved, the usability results from this preliminary study should not be reflective of the future usability results in the full WiSAT study.

The usability of WiSAT is an important aspect of the clinical protocol of the full study. For WiSAT to be viable and competitive when commercially available, the system needs to be user friendly and easy to operate independently. WiSAT is a unique and innovative piece of technology. Although there are similar products on the market, the WiSAT system has distinct features. WiSAT allows users to set their own goals and constantly change their goals for weight shift count per hour, activity score per hour, and time between shifts per hour, which is a feature unique to WiSAT. In addition, the products currently on the market, all display movement behavior differently. The benefit of WiSAT is that it quantifies the number of weight shifts the user does per hour, which requires virtually no interpretation by the user. One of the other products displays the angle of tilt of the wheelchair to the user, while another displays the pressure on sensors placed in the wheelchair cushion. Since each wheelchair user is different, it is great to have a wide variety of competing products on the market with diverse characteristics. This gives wheelchair users the opportunity to explore the different options and to find which product works the best for increasing their movement behavior.

5.3 MODIFICATIONS TO PROTOCOL

5.3.1 Inclusion Criteria

The inclusion criteria for the study were changed to be less restrictive and more reflective of the intended WiSAT population. It was changed to include individuals who (1) use a wheelchair, (2) are over the age of 18, (3) are at-risk for injuries, and (4) own a smartphone (Android operating system 5.0 or greater, iOS operating system of 9.0 or greater). At-risk for pressure injuries was defined by meeting at least one of the following:

1. Have a history of pressure ulcers on the buttocks.
2. The ability to walk is severely limited or non-existent. The individual cannot bear own weight and/or must be assisted into chair or wheelchair.
3. Have a combination of:
    a. Walks occasionally during day, but for very short distances, with or without assistance. Spends majority of day in wheelchair. AND
    b. Has sensory impairment which limits the ability to feel pain or discomfort over ½ of body, less sensation on left side with feeling.

During the recruitment screening process, it became apparent that the study's inclusion criteria were a limitation. WiSAT is a prevention tool to be used by anyone at risk for developing pressure injuries, but the current inclusion criteria did not reflect this idea. To be considered for being at risk of developing pressure injuries for the study, individuals were required to have a history of pressure injuries on their buttocks in the past 3 years AND a variation of a skin protection cushion. While the current inclusion criteria did assess a type of risk, they are focused on recent risk by restricting the pressure injury history to the past 3 years. The population that the WiSAT

system hopes to serve, is anyone at risk for pressure injuries, not just those with a more recent risk. For this reason, the 3-year time requirement was removed from the criteria. In addition, requiring individuals to have a skin protection cushion along with the history of pressure injuries makes the inclusion criteria even more restrictive. Medicare's policy states that an individual qualifies for a skin protection cushion if they (1) have or had a pressure ulcer in the buttocks region or (2) have a diagnosis involving a sensation impairment in the buttocks region or the inability to carry about a functional weight shift (Centers for Medicare & Medicad Services, 2019). Under Medicare's policy, if best practices were always executed, all individuals with a history of pressure injuries should have skin protection cushions; however, this is not always the case, limiting the current inclusion criteria further. Additionally, Medicare's policy may not address all the reasons an individual would be at an increased risk for developing pressure injuries, but it does illustrate that there are other key qualities, such as sensory impairment and inability to perform functional weight shifts, that put individuals at an increased-risk for pressure injuries. For these reasons, it was apparent that the inclusion criteria needed to modified to be less restrictive to allow more individuals at risk for pressure injuries to be included in the study.

To redefine risk for the inclusion criteria, a brief literature review was conducted. Through this review, it was revealed that Braden subscale scores are predictive of pressure injury risk and could be applied to the inclusion criteria. Subscales range from scores of 1 to 4, where 1 indicates highest risk. Since this study is aiming to recruit individuals who spend a majority of their time using a wheelchair, the activity subscale was assessed. The score of "2" (Chairfast: Ability to walk severely limited or nonexistent. Cannot bear own weight and/or must be assisted into chair or wheelchair.) most accurately fit the description of the population of users for the WiSAT system. Those who fall within this category are more likely to spend a majority of the day using a

wheelchair for mobility. In addition, the activity definition for a score of "3" (Walks Occasionally: Walks occasionally during day, but for very short distances, with or without assistance. Spends majority of each shift in bed or chair.) also had the potential of meeting the intended WiSAT population. This definition was paired with sensory perception to ensure participants were at an increased risk. As seen in the skin protection cushion Medicare policy, the inability to feel pain or sensation has been defined and accepted as a major risk factor of pressure injury development which is one reason this subscale was chosen over the other four. Also, it can be assessed through the phone screening process; many of the other Braden Scale subscales are more heavily impacted by the need of clinical judgment.

5.3.2 Equipment Updates

Georgia Tech consulted the app developers about the software issues. The app developers created an app update to remedy the issues pertaining to cellular data issue and the "Add Occupancy Algorithm" error. The cellular data issue was a quick fix; the update was pushed to the app store within the next week. On the other hand, the update to fix the "Add Occupancy Algorithm" took over a month to appear on the app store, leading to at least a month of missing data for the participant. In addition, the HaRI team redesigned the data portal to allow the University of Pittsburgh research team to access the participant's Error Log. This new design of the HaRI portal not only fixed this current situation, but it will also prevent the same issue from happening in the future.

Georgia Tech also handled the hardware problems. Georgia Tech's team is redesigning the 3D printed inductive charger case to reduce the strain on the charging cable. This will hopefully prevent future participants from needing new charging equipment during the home trial period.

Georgia Tech reported the data logger's internal clock issue to the hardware developers, Gulf Coast Data Concepts.

Since the WiSAT app had only been tested in lab with able-bodied subjects, it was important to conduct a feasibility trial to remedy these hardware and software issues. The data collection problems that were discovered during the feasibility trial of the protocol caused a lot of missing data for the participant. To fix some of these issues, the developers had to push app updates to the app store which can take weeks to be approved and available for download. Moreover, the research team made three trips out to the participant's home, completed two mailings of equipment to the participant, and participated in two video calls for troubleshooting purposes. It is important that these issues were resolved before recruiting additional participants to hopefully minimize missing data and extraneous troubleshooting sessions.

5.3.3 Active-Passive Decision Criteria

After the 2-week baseline period, the participants get to use the app and view their data for 4 weeks. Once these 4 weeks are up, it is decided if the participants go into active feedback mode or if they stay in passive feedback mode. This decision is based on whether or not they are meeting their goals, so to make this decision we had to define "meeting goals" for this 4-week period. To establish this criterion, the University of Pittsburgh team consulted and received input from both the Edward Hines Jr. VA Hospital site and Georgia Institute of Technology team.

To establish the criteria for the active-passive decision, the team considered some of the aspects and characteristics of using the app and the format of the app data. Since the goals' units are "quantity per hour", the team decided to analyze the data on the hourly level for this decision rather than averaging the data.

The next piece that was considered was the amount of time for the participant to become familiar with the app. As it may take a few days for the participants to learn how to use the different features of the app and find appropriate goals that reflect their data, it was decided to only use the participants' data for weeks 2, 3, and 4 (21 days) for the decision. This gives all participants one week (7 days) to fine tune their goal and get used to the app. In addition, the participants will be able to change their goal at any point during the 4-week passive feedback period. To ensure that participants are not penalized for adjusting their goal, data from the day the goal is changed will be excluded.

Furthermore, the team decided to exclude hours with low occupancy time (60 minutes divided by the participants' goal; e.g., 60 minutes / weight shift goal of 4 per hour = exclude any time under 15 minutes). The app reports the occupancy time and the number of weight shifts that occur during each hour of the day (1:00 pm – 2:00 pm, 2:00 pm – 3:00 pm, 3:00 pm – 4:00 pm, etc.) instead of during a full occupancy hour. Based on the data output, it is impossible to tell if the 10 minutes of occupancy time reported during 1:00 pm – 2:00 pm occurred from 1:00 pm to 1:10 pm, 1:50 pm – 2:00 pm, or in the middle of 1:00 pm – 2:00 pm. Due to this obscurity, low occupancy time was excluded from the analysis.

The last part of the criterion that needed to be decided was how often did the participant actually need to meet their goals. To help make this decision a literature review was conducted along with the review of data from four participants using the WiSAT equipment.

From analyzing the literature on in-seat behavior of wheelchair users, it is apparent that there is a need for the WiSAT system to aid individuals in reaching 3 weight shifts per hour (S. E. Sonenblum & Sprigle, 2018; Sharon E Sonenblum et al., 2016; S. Sprigle et al., 2019). The definition of weight shifts for the purposes of this study is equivalent to the combination of the

weight shifts and pressure reliefs as defined in the literature. In these previous studies, users tend to perform about 2 shifts per hour and at most 1 pressure relief, if any, per hour. This data indicates that the average user may not even meet the WiSAT app's minimum weight shift per hour goal of 3.

In addition to exploring the literature, a few test cases were observed at the University of Pittsburgh and Georgia Tech (Figure 13, Table 10). Based on this data, users may be more likely to hit the minimum goal of 3 weight shifts per hour. All participants averaged over 3 weight shifts per hour except one, who averaged 2.9 weight shift per hour over the use period. However, when the individual daily averages are observed there are 16 instances out of 46 days in which the participants are under 3 weight shifts per hour for their daily average, which is equivalent to about 65% of the time. This data was collected without the app and without setting goals, therefore, it cannot be directly applied to the decision criteria, but it is helpful on informing us of potential usage of the WiSAT equipment.

Based on the analysis of in-seat behavior, it is unlikely participants will meet their goal every hour of every day in the 21-day period. From this information and the fact that the purpose of the app is to help participants meet their weight shift goal, it was decided that participants will need to meet their goals 80% of the time. This 80% threshold will not include the low-occupancy hours that were previously mentioned to be excluded. The final criteria for the active-passive decision is as follows:

- To remain in passive feedback mode, the participant must meet their hourly goal for both weight shifts and activity score at least 80% of the time that they occupy their chair during weeks 2, 3, and 4 of viewing data (~21 days).

    - Week 1 will not be included. This will give the participant time to acclimate to using the app and seeing data on the app.
    - Hours that contain low occupancy time (60 min/weight shift goal, ex. 60/4 = 15 minutes) will be excluded.
    - If the participant changes their weight shift or activity score goals, the data on the day the goal changes will excluded. This allows the participant some extra time to adjust to the new goal.
- If the goals are not met 80% of time for both the weight shift score AND the activity score, the participant will be moved into active feedback mode and start receiving notifications.
    - If the participant meets the weight shift score goal 80% of the time they occupy their chair, but does not meet their activity score 80% of the time, they will be moved into active feedback mode.
    - If the participant meets the activity score goal 80% of the time they occupy their chair, but does not meet their weight shift score 80% of the time, they will be moved into active feedback mode.

Based on this criteria, the preliminary study participant remained in passive feedback mode. He met his weight shift goal 83.6% of the time and his activity score goal 84.2% of the time.

5.4 LIMITATIONS

The study had a few limitations. First, the study's sample size to test out the WiSAT system and clinical protocol was expected to be larger than one participant. However, due to issues with recruitment and the onset of the COVID-19 pandemic, only one participant was recruited. The pandemic caused the University of Pittsburgh study team to cancel scheduled participants' appointments and the team was unable to continue recruitment until further notice. This was unplanned and unexpected. The pandemic also affected the study team's ability to efficiently troubleshoot issues as they arose with the participant, leading to an increase of missing data.

Furthermore, it was difficult to determine the effect of the WiSAT system for a few different reasons. As previously mentioned, there was both a small sample size as well as the missing data.

Lastly, although the A-B single-subject analysis produced some interesting observations, this type of analysis can suffer from weak external and internal validity (Krishef, 1991; Ottenbacher, 1986). Due to the limited number of participants and the lack of random sampling in this design, it lacks external validity. As a result, the observations found in this preliminary study cannot be generalized to other subjects or populations. In addition, the A-B design also has some threats to internal validity. Since this design only involves two phases, the baseline and the intervention phase, it cannot be confirmed that the introduction of the intervention caused the changes observed. There could be other factors influencing the changes in behavior.

5.5 FUTURE WORK

The next step is to begin recruitment for the full WiSAT study. This will involve both sites, the University of Pittsburgh and the Edward Hines Jr. VA Hospital, recruiting their portion of the 76 participants targeted for the full study. This will enable the WiSAT system to receive more user feedback and design enhancement. Further, it will allow the impact of the system to be analyzed using more rigorous statistical methods.

Additionally, with the future analyses, the relationship between weight shift behavior and the PROMIS measures could be explored using regression statistical analyses. This type of analyses requires a sample size a good deal greater than one, so it could not be performed in this preliminary study. This is not currently a specific aim of the WiSAT study; however, since there is limited literature on how these concepts impact weight shift behavior, this analysis could provide valuable insight into the field.

5.6 CONCLUSION

WiSAT has the potential to help wheelchair users increase their in-seat movement and reduce their risk of developing pressure injuries. Although the effectiveness of the WiSAT system could not be determined with this preliminary study, this study aided in developing and testing the feasibility of the clinical protocol. The modifications and improvements made to the protocol will enable future participants in the WiSAT study to experience less complications and allow them to fully test the system with minimal issues to provide valuable design feedback.

Appendix A Demographics Survey

Demographics:	
1. Age:	_____ (years)
2. Weight:	_____ (lbs)
3. Height:	_____ (inches (e.g., 5 ft = 60 in))
4. Sex:	◯ Male ◯ Female
5. Ethnicity:	◯ Hispanic or Latino ◯ Not Hispanic or Latino
6. Race: (Select all that apply)	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or Other Pacific Islander ☐ White
7. What was the condition that caused you to use a wheelchair?	◯ Spinal Cord Injury ◯ Lower Extremity Amputation ◯ Spina Bifida ◯ Brain Injury ◯ Muscular Dystrophy ◯ Stroke ◯ Arthritis ◯ Cerebral Palsy ◯ Post-polio Syndrome ◯ Multiple Sclerosis ◯ Cardiopulmonary Disease ◯ Other
Please specify other:	_____
8. Current Occupation: (Select single best option)	◯ Paid employment ◯ Student ◯ Retired ◯ Unemployed (health reasons) ◯ Unemployed (other reasons) ◯ Other

Please specify other:	_____
9. Support Services: (You may select more than one option)	☐ Paid Caregiver (full-time, live in) ☐ Paid Caregiver (part-time) ☐ Service Connected Status (Veterans ONLY) ☐ Not applicable
10. Who do you live with? (You may select more than one option)	☐ Live alone ☐ Spouse ☐ Other family ☐ Friend ☐ Other
Please specify other:	_____

The following questions pertain to your technology use:

11. In the past month, have you used technology (e.g. personal computer, phone) for managing life activities ? (e.g., paying bills, monitoring financial accounts, making doctor appointments)	◯ Yes ◯ No
12. Do you monitor activity using a phone app? (e.g., Fitbit, food or sleep tracker)	◯ Yes ◯ No

The following questions pertain to your typical wheelchair use:

13. On average, how long do you sit each day (on all surfaces, including wheelchair)?	_____ (hours)
14. About how long do you sit in your wheelchair each day?	_____ (hours)
15. In a typical day, where do you sit outside of your wheelchair? (You may select more than one option)	☐ Household chairs (i.e. couch/recliner) ☐ Shower chair/ bench ☐ Vehicle seat ☐ Other wheelchairs ☐ Other surfaces
Please specify other surfaces:	_____
16. Do you ever use your wheelchair cushion outside of the wheelchair?	◯ Yes ◯ No
16a. For what activities do you use your wheelchair cushion outside of the wheelchair?	_____

17. How do you propel yourself in your wheelchair?	☐ Hands ☐ Feet ☐ Power controls (e.g., joystick, alternative drive controls) ☐ Power assist (e.g., SmartDrive, E-Motion Wheels) ☐ Rely on someone else to push wheelchair
18. For how long have you used a wheelchair?	_____ (years)

The following questions pertain to your pressure ulcer history:

19. Have you had recurrent pressure ulcers (a pressure ulcer heals and then becomes an active wound in the same location)?	◯ Yes ◯ No
20. How many pressure ulcers (sores) have you had on your buttocks in the past 3 years?	◯ 0 ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 or more
20a. In what locations did you experience the pressure ulcers (sores)? (You may select more than one option)	☐ Right Ischium (right buttock) ☐ Left Ischium (left buttock) ☐ Right Trochanter (right hip) ☐ Left Trochanter (left hip) ☐ Coccyx (middle of buttocks) ☐ Sacrum (upper center of buttocks) ☐ Other
Please specify other:	_____
20b. Do you currently have any pressure ulcers (sores) on your buttocks?	◯ Yes ◯ No
20b.1. Please specify the locations of your pressure ulcers (sores) that you currently have: (You may select more than one option)	☐ Right Ischium (right buttock) ☐ Left Ischium (left buttock) ☐ Right Trochanter (right hip) ☐ Left Trochanter (left hip) ☐ Coccyx (middle of buttocks) ☐ Sacrum (upper center of buttocks) ☐ Other
Please specify other:	_____

The following questions pertain to your weight shift behaviors:

21. What types of pressure reliefs do you perform regularly?
(You may select more than one option)

- ☐ Forward Lean
- ☐ Side Lean
- ☐ Partial Lift
- ☐ Complete Lift
- ☐ Tilt (using a manual tilt-in-space wheelchair)
- ☐ Tilt (power seat function of power wheelchair)
- ☐ Other

Please specify other: _____

22. How frequently do you perform pressure reliefs?

- ◯ Once every 15 minutes
- ◯ Every 15-30 minutes
- ◯ Every 30-60 minutes
- ◯ > Once every hour

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